PB81-112484

# Aspon: Pesticide Registration Standards O,O,O,O-Tetrapropyl Dithiopyrophosphate

(U.S.) Environmental Protection Agency
Arlington, VA

Sep 80

U.S. Department of Commerce
National Technical Information Service
NTIS.

United States
Environmental Protection
Agency

Office of
Pesticides and Toxic Substances
Washington DC 20460

PB81-112484

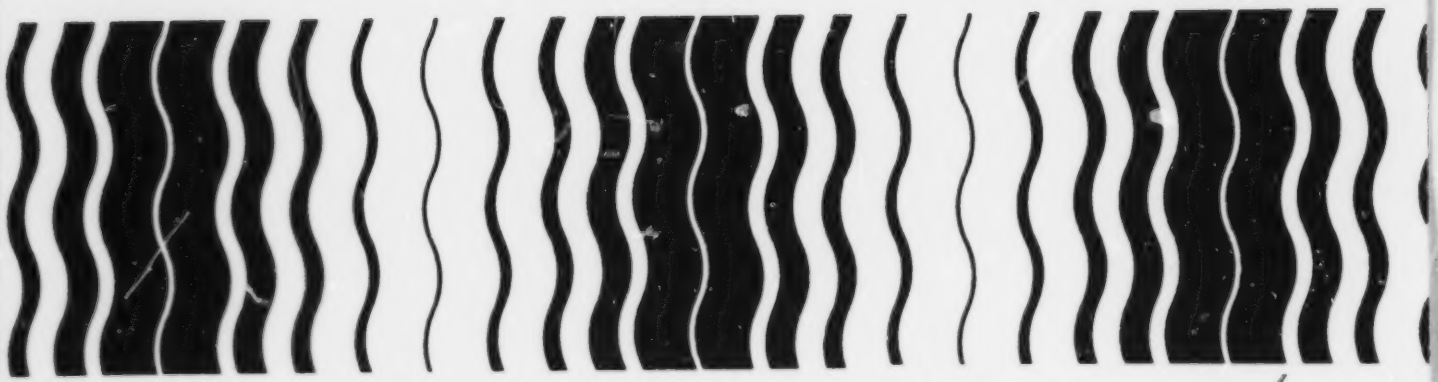
Pesticides

EPA

# 0,0,0,0-Tetrapropyl dithiopyrophosphate

# Aspon

## Pesticide Registration Standard



EPA/OPP-80/500

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INFORMATION SERVICE
U.S. DEPARTMENT OF COMMERCE
SPRINGFIELD, VA 22161

50272-101

| REPORT DOCUMENTATION PAGE | 1. REPORT NO. EPA/OPP-80/500 | 2. | 3. Recipient's Accession No. PB81-112484 |
|---|---|---|---|
| 4. Title and Subtitle<br>Aspon: Pesticide Registration Standards | | | 5. Report Date 9/80<br>6. |
| 7. Author(s) | | | 8. Performing Organization Rept. No. |
| 9. Performing Organization Name and Address<br>Environmental Protection Agency<br>Special Pesticide Review Division<br>Crystal Mall #2<br>Arlington, VA 22202 | | | 10. Project/Task/Work Unit No.<br>11. Contract(C) or Grant(G) No.<br>(C)<br>(G) |
| 12. Sponsoring Organization Name and Address<br>Environmental Protection Agency<br>401 M St. S.W.<br>Washington, D.C. 20460 | | | 13. Type of Report & Period Covered<br>14. |

15. Supplementary Notes

16. Abstract (Limit: 200 words)

A comprehensive statement of the Agency's regulatory position on all pesticide products containing the same active ingredient. The document discribes the data upon which the regulatory position is based, provides the rationale for the position and states the conditions which must be met to register a product under a standard.

17. Document Analysis a. Descriptors

0504,0606,0709

b. Identifiers/Open-Ended Terms

c. COSATI Field/Group

| 18. Availability Statement: Unlimited | 19. Security Class (This Report) Unclassified | 21. No. of Pages |
|---|---|---|
| | 20. Security Class (This Page) Unclassified | 22. Price |

(See ANSI-Z39.18) See Instructions on Reverse

OPTIONAL FORM 272 (4-77)
(Formerly NTIS-35)
Department of Commerce

# O,O,O,O-TETRAPROPYL DITHIOPYROPHOSPHATE

# ASPON®

## Pesticide Registration Standard


| | |
|---|---|
| Patrick Miller | Project Manager (SPRD) |
| John Bascietto | Wildlife Biologist (HED) |
| Charlotte Blalock | Residue Chemist (HED) |
| Padma Datta | Environmental Chemist (HED) |
| Roland Gessert | Toxicologist (HED) |
| Steve Hopkins | Plant Physiologist (HED) |
| William Miller | Product Manager (RD) |
| Randall Norris | Writer/Editor (SPRD) |
| Ingrid Sunzenauer | Entomologist (BFSD) |



September 1980

Office of Pesticides and Toxic Substances

Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

REGISTRATION STANDARD FOR ASPON®

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Chapter 1

# HOW TO REGISTER UNDER A REGISTRATION STANDARD

Organization of the Standard
Purpose of the Standard
Requirement to Re-register Under the Standard
"Product Specific" Data and "Generic" Data
Data Compensation Requirements under FIFRA 3(c)(1)(D)
Obtaining Data to Fill "Data Gaps"; FIFRA 3(c)(2)(B)
Amendments to the Standard

## Organization of the Standard

This first chapter explains the purpose of a Registration Standard and summarizes the legal principles involved in registering or re-registering under a Standard. The second chapter sets forth the requirements that must be met to obtain or retain registration for products covered by this particular Registration Standard. In the remaining chapters, the Agency reviews the available data by scientific discipline, discusses the Agency's concerns with the identified potential hazards, and logically develops the conditions and requirements that would reduce those hazards to acceptable levels.

## Purpose of the Standard

Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides that "no person in any State may distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive (and having so received) deliver or offer to deliver, to any person any pesticide which is not registered with the Administrator [of EPA]." To approve the registration of a pesticide, the Administrator must find, pursuant to Section 3(c)(5) that:

"(A) its composition is such as to warrant the proposed claims for it;
(B) its labeling and other material required to be submitted comply with the requirements of this Act;
(C) it will perform its intended function without unreasonable adverse effects on the environment; and
(D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment."

In making these findings, the Agency reviews a wide range of data which registrants are required to submit, and assesses the risks and benefits associated with the use of the proposed pesticide. But the established approach to making these findings has been found to be defective on two counts:

First, EPA and its predecessor agency, the United States Department of Agriculture (USDA), routinely reviewed registration applications on a 'product by product' basis, evaluating each product-specific application somewhat independently. In the review of products containing similar components, there was little opportunity for a retrospective review of the full range of pertinent data available in Agency files and in the public literature. Thus the 'product by product' approach was often inefficient and sometimes resulted in inconsistent or incomplete regulatory judgments.

Second, over the years, as a result of inevitable and continuing advances in scientific knowledge, methodology, and policy, the data base for many pesticides came to be considered inadequate by current scientific and regulatory standards. Given the long history of pesticide regulation in several agencies, it is even likely that materials may have been lost from the data files. When EPA issued new requirements for registration in 1975 (40 CFR 162) and proposed new guidelines for hazard testing in 1978 (43 FR 29686, July 10, 1978 and 43 FR 37336, August 2, 1978), many products that had already been registered for years were being sold and used without the same assurances of human and environmental safety as was being required for new products. Because of this inconsistency, Congress directed EPA to re-register all previously registered products, so as to bring their registrations and their data bases into compliance with current requirements [See FIFRA Section 3(g)].

Facing the enormous job of re-reviewing and calling-in new data for the approximately 35,000 current registrations, and realizing the inefficiencies of the 'product by product' approach, the Agency decided that a new, more effective method of review was needed.

A new review procedure has been developed. Under it, EPA publishes documents called Registration Standards, each of which discusses a particular pesticide active ingredient. Each Registration Standard summarizes all the data available to the Agency on a particular active ingredient and its current uses, and sets forth the Agency's comprehensive position on the conditions and requirements for registration of all existing and future products which contain that active ingredient. These conditions and requirements, all of which must be met to obtain or retain full registration or re-registration under Section 3(c)(5) of FIFRA, include the submission of needed scientific data which the Agency does not now have, compliance with standards of toxicity, composition, labeling, and packaging, and satisfaction of the data compensation provisions of FIFRA Section 3(c)(1)(D).

The Standard will also serve as a tool for product classification. As part of the registration of a pesticide product, EPA may classify each product for "general use" or "restricted use" [FIFRA Section 3(d)]. A pesticide is classified for "restricted use" when some special regulatory restriction is needed to ensure against unreasonable adverse effects to man or the environment. Many such risks of unreasonable adverse effects can be lessened if expressly-designed label precautions are strictly followed. Thus the special regulatory restriction for a "restricted use" pesticide is usually a requirement that it be applied only by, or under the supervision of, an applicator who has been certified by the State or Federal government as being competent to use pesticides safely, responsibly, and in accordance with label directions. A restricted-use pesticide can have other regulatory restrictions [40 CFR 162.11(c)(5)] instead of, or in addition to, the certified applicator requirement. These other regulatory restrictions may include such actions as seasonal or regional limitations on use, or a requirement for the monitoring of residue levels after use. A pesticide classified for "general use," or not classified at all, is available for use by any individual who is in compliance with State or local regulations. The Registration Standard review compares information about potential adverse effects of specific uses of the pesticide with risk criteria listed in 40 CFR 162.11(c), and thereby determines whether a product needs to be classified for "restricted use." If the Standard does classify a pesticide for "restricted use," this determination is stated in the second chapter.

## Requirement to Re-register Under the Standard

FIFRA Section 3(g), as amended in 1978, directs EPA to re-register all currently registered products as expeditiously as possible. Congress also agreed that re-registration should be accomplished by the use of Registration Standards.

Each registrant of a currently registered product to which this Standard applies, and who wishes to continue to sell or distribute his product in commerce, must apply for re-regisration. His application must contain proposed labeling that complies with this Standard.

EPA will issue a notice of intent to cancel the registration of any currently registered product to which this Standard applies if the registrant fails to comply with the procedures for re-registration set forth in the Guidance Package which accompanies this Standard.

## "Product Specific" Data and "Generic" Data

In the course of developing this Standard, EPA has determined the types of data needed for evaluation of the properties and effects of products to which the Standard applies, in the disciplinary areas of Product Chemistry, Environmental Fate, Toxicology, Residue Chemistry, and Ecological Effects. These determinations are based primarily on the data Guidelines proposed in 1978 (43 FR 29686, July 10, 1978, and 43 FR 37336, August 2, 1978), as applied to the use patterns of the products to which this Standard applies. Where it appeared that data from a normally applicable Guidelines requirement was actually unnecessary to evaluate these products, the Standard indicates that the requirement has been waived. On the other hand, in some cases studies not required by the Guidelines may be needed because of the particular composition or use pattern of products the Standard covers; if so, the Standard explains the Agency's reasoning. Data guidelines have not yet been proposed for the Residue Chemistry discipline, but the requirements for such data have been in effect for some time and are, the Agency believes, relatively familiar to registrants. Data which we have found are needed to evaluate the registrability of some products covered by the Standard may not be needed for the evaluation of other products, depending upon the composition, formulation type, and intended uses of the product in question. The Standard states which data requirements apply to which product categories. (See the second chapter.)

The various kinds of data normally required for registration of a pesticide product can be divided into two basic groups:

(A) data that is "product specific," i.e., data that relates only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition); and

(B) "generic" data that pertains to the properties or effects of a particular ingredient, and thus is relevant to an evaluation of the risks and benefits of all products containing that ingredient (or all such products having a certain use pattern), regardless of any such product's unique composition.

The Agency requires certain "product specific" data for each product to characterize the product's particular composition and physical/chemical properties (Product Chemistry), and to characterize the product's acute toxicity (which is a function of its total composition). The applicant for registration or re-registration of any product, whether it is a manufacturing-use or end-use product, and without regard to its intended use pattern, must

submit or cite enough of this kind of data to allow EPA to evaluate the product. For such purposes, "product specific" data on any product other than the applicant's is irrelevant, unless the other product is closely similar in composition to the applicant's. (Where it has been found practicable to group similar products for purposes of evaluating, with a single set of tests, all products in the group, the Standard so indicates.) "Product specific" data on the efficacy of particular end-use products is also required where the exact formulation may affect efficacy and where failure of efficacy could cause public health problems.

All other data needed to evaluate pesticide products concerns the properties or effects of a particular ingredient of products (normally a pesticidally active ingredient, but in some cases a pesticidally inactive, or "inert," ingredient). Some data in this "generic" category are required to evaluate the properties and effects of all products containing that ingredient [e.g., the acute LD-50 of the active ingredient in its technical or purer grade; see proposed 40 CFR 163.81-1(a), 43 FR 37355].

Other "generic" data are required to evaluate all products which both contain a particular ingredient and are intended for certain uses (see, e.g., proposed 40 CFR 163.82-1, 43 FR 37363, which requires subchronic oral testing of the active ingredient with respect to certain use patterns only). Where a particular data requirement is use-pattern dependent, it will apply to each end-use product which is to be labeled for that use pattern (except where such end-use product is formulated from a registered manufacturing-use product permitting such formulations) and to each manufacturing-use product with labeling that allows it to be used to make end-use products with that use pattern. Thus, for example, a subchronic oral dosing study is needed to evaluate the safety of any manufacturing-use product that legally could be used to make an end-use, food-crop pesticide. But if an end-use product's label specified it was for use only in ways that involved no food/feed exposure and no repeated human exposure, the subchronic oral dosing study would not be required to evaluate the product's safety; and if a manufacturing-use product's label states that the product is for use only in making end-use products not involving food/feed use or repeated human exposure, that subchronic oral study would not be relevant to the evaluation of the manufacturing-use product either.

If a registrant of a currently registered manufacturing-use or end-use product wishes to avoid the costs of data compensation [under FIFRA Section 3(c)(1)(D)] or data generation [under Section 3(c)(2)(B)] for "generic" data that is required only with respect to some use patterns, he may elect to delete those use patterns from his labeling at the time he re-registers his product. An applicant for registration of a new product under this Standard may similarly request approval for only certain use patterns.

## Data Compensation Requirements under FIFRA 3(c)(1)(D)

Under FIFRA Section 3(c)(1)(D), an applicant for registration, re-registration, or amended registration must offer to pay compensation for certain existing data the Agency has used in developing the Registration Standard. The data for which compensation must be offered is all data which is described by all the following criteria:

(1) the data were first submitted to EPA (or to its predecessor agencies, USDA or FDA), on or after January 1, 1970;
(2) the data were submitted to EPA (or USDA or FDA) by some other applicant or registrant in support of an application for an

experimental use permit, an amendment adding a new use to a registration, or for re-registration, or to support or maintain in effect an existing registration;

(3) the data are relevant to the Agency's decision to register or re-register the applicant's product under the Registration Standard, taking into account the applicant's product's composition and intended use pattern(s);

(4) the data are determined by EPA to be valid and usable in reaching regulatory conclusions; and

(5) the data are not those for which the applicant has been exempted by FIFRA Section 3(c)(2)(D) from the duty to offer to pay compensation. (This exemption applies to the "generic" data concerning the safety of an active ingredient of the applicant's product, not to "product specific" data. The exemption is available only to applicants whose product is labeled for end-uses for which the active ingredient in question is present in the applicant's product because of his use of another registered product containing that active ingredient which he purchases from another producer.)

An applicant for re-registration of an already registered product under this Standard, or for registration of a new product under this Standard, accordingly must determine which of the data used by EPA in developing the Standard must be the subject of an offer to pay compensation, and must submit with his application the appropriate statements evidencing his compliance with FIFRA Section 3(c)(1)(D).

An applicant would never be required to offer to pay for "product specific" data submitted by another firm. In many, if not in most cases, data which are specific to another firm's product will not suffice to allow EPA to evaluate the applicant's product, that is, will not be useful to the Agency in determining whether the applicant's product is registrable. There may be cases, however, where because of close similarities between the composition of two or more products, another firm's data may suffice to allow EPA to evaluate some or all of the "product specific" aspects of the applicant's product. In such a case, the applicant may choose to cite that data instead of submitting data from tests on his own product, and if he chooses that option, he would have to comply with the offer-to-pay requirements of Section 3(C)(1)(D) for that data.

Each applicant for registration or re-registration of a manufacturing-use product, and each applicant for registration or re-registration of an end-use product, who is not exempted by FIFRA Section 3(c)(2)(D), must comply with the Section 3(c)(1)(D) requirements with respect to each item of "generic" data that relates to his product's intended uses.

A detailed description of the procedures an applicant must follow in applying for re-registration (or new registration) under this Standard is found in the Guidance Package for this Standard.

## Obtaining Data to Fill "Data Gaps"; FIFRA 3(c)(2)(B)

Some of the kinds of data EPA needs for its evaluation of the properties and effects of products to which this Standard applies have never been submitted to the Agency (or, if submitted, have been found to have deficiencies rendering them inadequate for making registrability decisions) and have not been located in the published literature search that EPA conducted as part of preparing this Standard. Such instances of missing but required data are referred to in the Standard as "data gaps".

FIFRA Section 3(c)(2)(B), added to FIFRA by the Congress in 1978, authorizes EPA to require registrants to whom a data requirement applies to generate (or otherwise produce) data to fill such "gaps" and submit those data to EPA. EPA must allow a reasonably sufficient period for this to be accomplished. If a registrant fails to take appropriate and timely steps to fill the data gaps identified by a section 3(c)(2)(B) order, his product's registration may be suspended until the data are submitted. A mechanism is provided whereby two or more registrants may agree to share in the costs of producing data for which they are both responsible.

The Standard lists, in its summary second chapter, the "generic" data gaps and notes the classes of products to which these data gaps pertain. The Standard also points out that to be registrable under the Standard, a product must be supported by certain required "product specific" data. In some cases, the Agency may possess sufficient "product specific" data on one currently registered product, but may lack such data on another. Only those Standards which apply to a very small number of currently registered products will attempt to state definitively the "product specific" data gaps on a 'product by product' basis. (Although the Standard will in some cases note which data that EPA does possess would suffice to satisfy certain "product specific" data requirements for a category of products with closely similar composition characteristics.)

As part of the process of re-registering currently registered products, EPA will issue Section 3(c)(2)(B) directives requiring the registrants to take appropriate steps to fill all identified data gaps -- whether that data in question is "product specific" or "generic" -- in accordance with a schedule.

Persons who wish to obtain registrations for new products under this Standard will be required to submit (or cite) sufficient "product specific" data before their applications are approved. Upon registration, they will be required under Section 3(c)(2)(B) to take appropriate steps to submit data needed to fill "generic" data gaps. (We expect they will respond to this requirement by entering into cost-sharing agreements with other registrants who previously have been told they must furnish the data.) The Guidance Package for this Standard details the steps that must be taken by registrants to comply with Section 3(c)(2)(B).

## Amendments to the Standard

Applications for registration which propose uses or formulations that are not presently covered by the Standard, or which present product compositions, product chemistry data, hazard data, toxicity levels, or labeling that do not meet the requirements of the Standard, will automatically be considered by the Agency to be requests for amendments to the Standard. In response to such applications, the Agency may request additional data to support the proposed amendment to the Standard, or may deny the application for registration on the grounds that the proposed product would cause unreasonable adverse effects to the environment. In the former case, when additional data have been satisfactorily supplied, and providing that the data do not indicate the potential for unreasonable adverse effects, the Agency will then amend the Standard to cover the new registration.

Each Registration Standard is based upon all data and information available to the Agency's reviewers on a particular date prior to the publication date. This "cut-off" date is stated at the beginning of the second chapter. Any subsequent data submissions and any approved amendments will be incorporated into the Registration Standard by means of addenda, which are available for inspection at EPA in Washington, D.C., or copies of which may be requested from

the Agency. When all the present "data gaps" have been filled and the submitted data have been reviewed, the Agency will revise the Registration Standard. Thereafter, when the Agency determines that the internally maintained addenda have significantly altered the conditions for registration under the Standard, the document will be updated and re-issued for publication.

While the Registration Standard discusses only the uses and hazards of products containing the designated active ingredient(s), the Agency is also concerned with the potential hazards of some inert ingredients and impurities. Independent of the development of any one Standard, the Agency has initiated the evaluation of some inert pesticide ingredients. Where the Agency has identified inert ingredients of concern in a specific product to which the Standard applies, these ingredients will be pointed out in the Guidance Package.

## REGULATORY POSITION

This chapter presents the Agency's decision on what Standards of product composition, toxicity, use, labeling, and packaging are required for the pesticide active ingredient in question. The decision complies with the rules and regulations (40 CFR 162) used to implement the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA), and with the Agency's present regulatory policies. There are different requirements for manufacturing-use chemicals and for each type of end-use formulation which present a significantly different set of hazards. This Registration Standard is based upon all data and information on Aspon®* available to the Agency's reviewers as of February 27, 1979.

Companies which have submitted data in support of their registrations of Aspon® products are Chevron Chemical Company and Stauffer Chemical Company, both of Richmond, Calif., and O.M. Scott & Sons of Marysville, Ohio. These data may be cited by other registrants or applicants for registration, when appropriate, to support the registration(s) of their own product(s), provided they have offered and

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* Aspon® is a registered trade name of Stauffer Chemical Company. Its use in this document does not constitute endorsement or recommendation for use by this Agency. Since there is no acceptable common name for this compound, the trade name will be used in this document for convenience.



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agreed to pay compensation, as required by FIFRA Sections 3(c)(1)(d) and 3(c)(2)(d).

Manufacturing-Use Aspon®

The Agency has reviewed all data available to it. Although incomplete, these data indicate that manufacturing-use Aspon® (which includes both the technical material and the granular formulation intermediate) is suitable for registration because it does not meet or exceed the risk criteria leading to a Rebuttable Presumption Against Registration [Chapter 40, Section 162.11(a) of the Code of Federal Regulations]. Data gaps have been identified; when these data are supplied, the Agency will again review the registration status of this compound.

In order to be covered under this Standard, a manufacturing-use Aspon® product must comply with the following standards. A manufacturing-use Aspon® product must contain Aspon® (O,O,O,O-Tetrapropyl dithiopyrophosphate) as an active ingredient. Given current manufacturing-use product grades and formulation methods, the Agency expects that most technical material will range above 90% a.i. and that most granular formulation intermediates will range above 25% a.i. Should an applicant desire to register a manufacturing-use product that departs greatly from those currently registered, that applicant should contact the Agency for specific directions on how to accomplish registration. Because Aspon® is corrosive to steel, manufacturers of the technical material may not ship it in unlined steel containers. The

acute toxicology testing on a manufacturing-use Aspon® product must demonstrate into which Toxicity Category (I through IV) the product falls for the following acute effects:

Acute Oral Toxicity;

Acute Dermal Toxicity;

Acute Inhalation Toxicity;

Primary Eye Irritation; and

Primary Dermal Irritation.

Labels for currently registered manufacturing-use Aspon® products must include the following:

1. The intended end-use of products formulated from manufacturing-use products determines which data applicants for (re)registration of the manufacturing-use product are required to submit or cite. All manufacturing-use Aspon® products must therefore carry one of the following statements on the label:

a. For Formulation Into End-Use Insecticide Products Intended Only for Domestic, Non-Food, Outdoor Use;

b. For Formulation Into End-Use Insecticide Products Intended Only for Non-Domestic, Non-Food, Outdoor Use; or

c. For Formulation Into End-Use Insecticide Products Intended Only for Domestic or Non-Domestic, Non-Food, Outdoor Use.

2. All manufacturing-use Aspon® products must carry the following warning on the label, under the "Hazards to Wildlife" section:

> This pesticide is toxic to fish. Do not discharge into lakes, streams, ponds, or public water unless in accordance with NPDES permit. For guidance, contact your Regional Office of the EPA.

3. All technical Aspon® products must carry the following warning on the label:

> This product is corrosive to steel. Do not transport or store in unlined steel containers.

4. Manufacturing-use product labels must comply with the requirements of 40 CFR 162.10 regarding label format, including placement of hazard warnings on the label, type size and color, etc.

To be covered under this Standard, all applicants for registration or re-registration of technical and formulation intermediate products must agree to cite or submit the following information on the composition and toxicity of each proposed product. After each data gap is listed the section in the Proposed Guidelines which describes that type of data and when it is required [43 FR, No. 132, 29696 of July 10, 1978; and 43 FR, No. 163, 37336 of August 22, 1978]. While the Agency does have some limited data on the product chemistry of Aspon®, possible changes in the manufacturing processes or product formulation methods may

affect the product's physical/ chemical characteristics. All normally required data on physical/chemical characteristics are therefore being listed as data gaps, so that the Agency can obtain the most current data.

| | Guidelines Section |
|---|---|
| Product Chemistry | |
| For Both Technical and Formulation Intermediate | |
| 1) Product Identity | 163.61-3(a) |
| 2) Disclosure of Ingredients | 163.61-3(c) |
| 3) Description of Manufacturing Process | 163.61-4 |
| 4) Formation of Unintentional Ingredients | 163.61-5 |
| 5) Declaration of Limits | 163.61-6(a) |
| 6) Certification of Limits | 163.61-6(b) |
| 7) Analytical Methods | 163.61-7(a) |
| 8) Analytical Results | 163.61-7(b)(1) |
| For Technical | |
| 9) Color | 163.61-8(c)(1) |
| 10) Odor | 163.61-8(c)(2) |
| 11) Melting Point | 163.61-8(c)(3) |
| 12) Solubility (in quantitative terms) | 163.61-8(c)(4) |
| 13) Stability | 163.61-8(c)(5) |
| 14) Octanol/Water Partition Coefficient | 163.61-8(c)(6) |
| 15) Physical State | 163.61-8(c)(7) |
| 16) Density or Specific Gravity | 163.61-8(c)(8) |
| 17) Boiling Point | 163.61-8(c)(9) |
| 18) Vapor Pressure | 163.61-8(c)(10) |
| 19) pH | 163.61-8(c)(11) |
| For Formulation Intermediate | |
| 20) Density or Specific Gravity | 163.61-8(c)(8) |
| 21) Storage Stability | 163.61-8(c)(12) |
| 22) Flammability | 163.61-8(c)(13) |
| 23) Oxidizing or Reducing Action | 163.61-8(c)(14) |
| 24) Explosiveness | 163.61-8(c)(15) |
| 25) Corrosion Characteristics | 163.61-8(c)(18) |

| | Guidelines Section |
|---|---|
| *Toxicology | |
| 1) Acute Oral Toxicity Study..... | 163.81-1 |
| 2) Acute Dermal Toxicity Study..... | 163.81-2 |
| 3) Acute Inhalation Toxicity Study... | 163.81-3 |
| 4) Primary Eye Irritation Study..... | 163.81-4(c) |
| OR | |
| Data on pH of the Product..... | 163.81-4(b) |
| 5) Primary Dermal Irritation Study... | 163.81-5 |
| 6) Dermal Sensitization Study..... | 163.81-6 |

To be covered under this Standard, applicants for registration or re-registration of technical and formulation intermediate products which are labeled for formulation into products intended for non-domestic or domestic, outdoor, non-food, use must agree to submit or cite all of the information required above, as well as the following information:

Non-Domestic or Domestic Use

| | Guidelines Section |
|---|---|
| Environmental Fate | |
| 1) Hydrolysis..... | 163.62-7(b) |
| 2) Photolysis (in water)..... | 163.62-7(c) |
| 3) Aerobic Soil Metabolism..... | 163.62-8(b) |
| 4) Microbial Metabolism..... | 163.62-8(f)(2) |
| 5) Activated Sludge Metabolism..... | 163.62-8(g) |
| 6) Leaching..... | 163.62-9(b) |
| 7) Adsorption/Desorption..... | 163.62-9(d) |
| 8) Field Dissipation study on representative emulsifiable concentrate and granular formulations..... | 163.62-10 |
| 9) Fish Accumulation..... | 163.62-11(d) |
| Toxicology | |
| 1) Teratogenicity Study..... | 163.83-3 |
| 2) Acute Delayed Neurotoxicity..... | 163.81-7 |

* A demonstration that a manufacturing-use Aspon® product has a composition substantially similar to a manufacturing-use product for which the Agency already has acceptable acute toxicity data will satisfy acute toxicity data requirements for the former product. Both active and inert ingredients will be considered in making determinations of similarity.

| | Guidelines Section |
|---|---|
| Ecological Effects | |
| 1) Microbial Metabolism..... | 163.62-8(f)(3) |
| 2) The avian acute oral LD-50 for one species of waterfowl (preferably the mallard) or one species of upland game bird (preferably the bobwhite, other native quail, or the ring-necked pheasant)..... | 163.71-1 |
| 3) A 48-hour LC-50 (or EC-50) for one species of aquatic invertebrate (preferably Daphnia magna).. | 163.72-2 |

Emulsifiable Concentrate Aspon®

In order to be covered under this Standard, an end-use emulsifiable concentrate (EC) Aspon® product must contain Aspon® (O,O,O,O-Tetrapropyl dithiopyrophosphate) as an active ingredient. FIFRA Section 162.11(c) lists the criteria for classifying pesticides for restricted, non-domestic, or domestic use.

EC Aspon® products which are shown to have a Toxicity Category I rating for any of the following acute effects must be classified for restricted use (i.e., for retail sale to and application only by certified applicators or persons under their direct supervision):

Acute Oral Toxicity;

Acute Dermal Toxicity; or

Acute Inhalation Toxicity.

EC Aspon® products which are shown to have a Toxicity Category II rating for any of the following acute effects must be classified for non-domestic use:

Acute Oral Toxicity;

Acute Dermal Toxicity; or

Acute Inhalation Toxicity.

EC Aspon® products which are shown to have any of the following Toxicity Category ratings may be classified for domestic use:

Acute Oral Toxicity: Category III or IV

Acute Dermal Toxicity: Category III or IV

Acute Inhalation Toxicity: Category III or IV

Primary Eye Irritation: Category I through IV

Primary Dermal Irritation: Category I through IV

EC products intended for domestic use with Toxicity Category I or II ratings for primary eye or dermal irritation must meet the criteria for child-resistant packaging [see FR 44(48):13019-13024, March 9, 1979].

Labels for currently registered EC Aspon® products must include the following:

1. If EC Aspon® products contain petroleum distillates, the statement "Contains petroleum distillates" must appear on the label in close proximity to the ingredient statement.

Active ingredient:
O,O,O,O-Tetrapropyl dithiopyrophosphate..... %
Inert Ingredients*..... %
Total..... 100%
*Contains Petroleum Distillates

2. If the EC Aspon® product has an Acute Oral Toxicity Category IV and contains greater than 10% by weight petroleum distillates, the following first aid statement must appear on the label (see also Table 2, Appendix A):

If swallowed: If the patient is unconscious, maintain breathing and heart rate (CPR:cardiopulmonary resuscitation). Contact your local Poison Control Center, physician, or hospital immediately. Do Not Induce Vomiting!

If the EC Aspon® product has an Acute Oral Toxicity Category I and contains greater than 10% by weight petroleum distillates, the following first aid statement must appear on the label (see also Table 2, Appendix A):

If swallowed: If the patient is unconscious, maintain breathing and heart rate (CPR:cardiopulmonary resuscitation). Contact your local Poison Control Center, physician, or hospital immediately. If the patient is conscious, induce vomiting (syrup of ipecac; if not available, stimulate the back of the throat with finger). Never give anything by mouth to an unconscious person!

If the EC Aspon® product has an Acute Oral Toxicity Category II or III and contains greater than 10% by weight petroleum distillates, the following first aid statement must appear on the label (see also Table 2, Appendix A):

If swallowed: If the patient is unconscious, maintain breathing and heart rate (CPR:cardiopulmonary resuscitation). Contact your local Poison Control Center, physician, or hospital immediately.

The question of whether vomiting should or should not be induced will be determined on a case-by-case basis based on a review of the toxicity of active ingredients, inert ingredients, and impurities.

3. All EC Aspon® products must carry the following warning on the label:

Keep children and pets off treated areas for 48 hours after application and until the grass has completely dried.

4. All EC Aspon® products must carry the following warning on the label, under the "Hazards to Wildlife" section:

This pesticide is toxic to fish. Do not contaminate water by cleaning of equipment or disposal of wastes.

5. All currently registered EC Aspon® products between 12% and 28% a.i. must carry on the label the acute toxicity hazard warnings and first aid statements required for the following Toxicity Categories (see Appendix A):

Acute Dermal Toxicity - III

Primary Eye Irritation - I

Primary Dermal Irritation - II

6. EC product labels must comply with the requirements of 40 CFR 162.10 regarding label format, including placement of hazard warnings on the label, type size and color, etc. In addition, all labels and labeling intended for agricultural uses must bear the statement, "This product must be applied in accordance with 40 CFR 170." (Registrants may amplify

this statement on labels or labeling by stating the requirements of 40 CFR Part 170 or additions thereto if they choose.)

To be covered under this Standard, all applicants for registration or reregistration of EC Aspon® products must agree to submit or cite the following information on the composition of each proposed product. After each data gap is listed the section in the Proposed Guidelines which describes that type of data and when it is required [43 FR, No. 132, 29696 of July 10, 1978; and 43 FR, No. 163, 37336 of August 22, 1978].

| | Guidelines Section |
|---|---|
| Product Chemistry | |
| 1) Product Identity | 163.61-3(a) |
| 2) Disclosure of Ingredients | 163.61-3(c) |
| 3) Description of Manufacturing Process | 163.61-4 |
| 4) Formation of Unintentional Ingredients | 163.61-5 |
| 5) Declaration of Limits | 163.61-6(a) |
| 6) Certification of Limits | 163.61-6(b) |
| 7) Analytical Methods | 163.61-7(a) |
| 8) Analytical Results | 163.61-7(b)(1) |
| 9) Color | 163.61-8(c)(1) |
| 10) Odor | 163.61-8(c)(2) |
| 11) Density or Specific Gravity | 163.61-8(c)(8) |
| 12) Storage Stability | 163.61-8(c)(12) |
| 13) Flammability | 163.61-8(c)(13) |
| 14) Oxidizing or Reducing Action | 163.61-8(c)(14) |
| 15) Explosiveness | 163.61-8(c)(15) |
| 16) Miscibility | 163.61-8(c)(16) |
| 17) Viscosity | 163.61-8(c)(17) |
| 18) Corrosion Characteristics | 163.61-8(c)(18) |
| 19) Dielectric Breakdown Voltage | 163.61-8(c)(19) |

Listed below are the Toxicology data which must be submitted or cited to obtain registration or re-registration for EC Aspon® products. After each data gap is listed the Section in the Proposed Guidelines of August 22, 1978 (43 FR, No. 163, 37336) which describes that type of data and when it is required. The Agency has determined that currently

registered EC products between 12% and 28% a.i. are substantially similar in composition, and that EC products between 65% and 68% a.i. are substantially similar in composition. Acute toxicity data available on any one product in either group may be cited in support of the registration of any other product in that group, provided compensation has been offered for use of these data. Currently registered EC Aspon® products which contain other active ingredients must be tested individually for each acute effect.

| | Guidelines Section |
|---|---|
| **ECs Between 12% and 28% a.i.*** | |
| 1) Acute oral toxicity (rat) on product in upper range (i.e., @ 25% a.i.) | 163.81-1 |
| 2) Acute inhalation (rat) on product in upper range (i.e., @ 25% a.i.) | 163.81-3 |
| **ECs Between 65% and 68% a.i.*** | |
| 1) Acute oral toxicity (rat) | 163.81-1 |
| 2) Acute dermal toxicity (rabbit) | 163.81-2 |
| 3) Acute inhalation (rat) | 163.81-3 |
| 4) Primary eye irritation (rabbit) | 163.81-4(c) |
| OR | |
| Data on pH of the Product | 163.81-4(b) |
| 5) Primary skin irritation (rabbit) | 163.81-5 |
| **ECs With Aspon® and Other Active Ingredients** | |
| 1) Acute oral toxicity (rat) | 163.81-1 |
| 2) Acute dermal toxicity (rabbit) | 163.81-2 |
| 3) Acute inhalation (rat) | 163.81-3 |

* A demonstration that an EC Aspon® product has a composition substantially similar to an EC product for which the Agency already has acceptable acute toxicity data will satisfy acute toxicity data requirements for the former product. Both active and inert ingredients will be considered in making determinations of similarity.

| | Guidelines Section |
|---|---|
| 4) Primary eye irritation (rabbit)..... | 163.81-4(c) |
| OR | |
| Data on pH of the Product.... | 163.81-4(b) |
| 5) Primary skin irritation (rabbit)..... | 163.81-5 |

Granular Aspon®

In order to be covered under this Standard, an end-use granular Aspon® product must contain Aspon® (O,O,O,O-Tetrapropyl dithiopyrophosphate) as an active ingredient. FIFRA Section 162.11(c) lists the criteria for classifying pesticides for restricted, non-domestic, or domestic use.

Granular Aspon® products which are shown to have a Toxicity Category I rating for any of the following acute effects must be classified for restricted use (i.e., for retail sale to and application only by certified applicators or persons under their direct supervision):

Acute Oral Toxicity;

Acute Dermal Toxicity; or

Acute Inhalation Toxicity.

Granular Aspon® products which are shown to have a Toxicity Category II rating for any of the following acute effects must be classified for non-domestic use:

Acute Oral Toxicity;

Acute Dermal Toxicity; or

Acute Inhalation Toxicity.

Granular Aspon® products which are shown to have any of the following toxicity Category ratings may be classified

for domestic use:

Acute Oral Toxicity: Category III or IV

Acute Dermal Toxicity: Category III or IV

Acute Inhalation Toxicity: Category III or IV

Primary Eye Irritation: Category I through IV

Primary Dermal Irritation: Category I through IV

Granular products intended for domestic use with Toxicity Category I or II ratings for primary eye or dermal irritation must meet the criteria for child-resistant packaging [see FR 44(48):13019-13024, March 9, 1979].

Labels for currently registered granular Aspon® products must include the following:

1. All granular Aspon® products must carry the following warning on the label:

Keep children and pets off treated areas for 48 hours after application and until the grass has completely dried.

2. All granular Aspon® products must carry the following warning on the label, under the "Hazards to Wildlife" section:

This pesticide is toxic to fish. Do not contaminate water by cleaning of equipment or disposal of wastes.

3. All currently registered granular Aspon® products between 1% and 5% a.i. must carry on the label the acute toxicity hazard warnings and first aid statements required for the following Toxicity Categories (see Appendix A).

Without Fertilizer
1) Acute Oral Toxicity - III
2) Acute Dermal Toxicity - III
3) Primary Eye Irritation - III
4) Primary Dermal Irritation - III

With Fertilizer
1) Acute Oral Toxicity - III
2) Acute Dermal Toxicity - III
3) Primary Eye Irritation - II
4) Primary Dermal Irritation - III

4. Granular product labels must comply with the requirements of 40 CFR 162.10 regarding label format, including placement of hazard warnings on the label, type size and color, etc. In addition, all labels and labeling intended for agricultural use must bear the following statement, "This product must be applied in accordance with 40 CFR 170." (Registrants may amplify this statement on labels or labeling by stating the requirements or 40 CFR Part 170 or additions thereto if they choose.)

To be covered under this Standard, all applicants for registration or reregistration of granular Aspon® products must agree to submit or cite the following information on the composition of each proposed product. After each data gap is listed the section in the Proposed Guidelines which describes that type of data and when it is required [43 FR, No. 132, 29696 of July 10, 1978; and 43 FR, No. 163, 37336 of August 22, 1978].

| | Guidelines Section |
|---|---|
| Product Chemistry | |
| 1) Product Identity | 163.61-3(a) |
| 2) Disclosure of Ingredients | 163.61-3(c) |
| 3) Description of Manufacturing Process | 163.61-4 |
| 4) Formation of Unintentional Ingredients | 163.61-5 |
| 5) Declaration of Limits | 163.61-6(a) |

[Footnote concluded from previous page.]

** An acute inhalation toxicity study is required for granular products if "20 percent or more of the aerodynamic equivalent of the formulated product (as registered or under conditions of use) is composed of particulates not larger than 10 microns in diameter" [Guidelines Section 163.81-3(a)(2)(ii)]. An acute inhalation test on any currently registered granular product between 1% and 6% a.i. may be submitted or cited in support of the registrations of all currently registered granular products. A request for a waiver of this requirement based on percent of particulates not larger than 10 microns must be made individually for each product.

## MANUFACTURING-USE ASPON®
## (TECHNICAL AND FORMULATION INTERMEDIATE)

### I. Regulatory Position

#### A. Regulatory Decision

The Agency has reviewed all data available to it. Although incomplete, these data indicate that manufacturing-use Aspon® is suitable for registration because it does not meet or exceed the risk criteria leading to a Rebuttable Presumption Against Registration [Chapter 40, Section 162.11(a) of the Code of Federal Regulations]. Data gaps have been identified; when these data are supplied, the Agency will again review the registration status of this compound.

The Agency has determined that manufacturing-use Aspon® does not appear to cause an unreasonable adverse effect with proper label directions and precautions. Those manufacturing-use products currently registered may be reregistered subject to the conditions imposed for data requirements, and new products may also be registered under the terms of this Standard.

#### B. Criteria for Registration Under the Standard

To be registered under this Standard, manufacturing-use Aspon® products must meet the following conditions:

1. The manufacturing-use product contains Aspon® as an active ingredient;

2. The manufacturing-use product bears required labeling;

3. The manufacturing-use product must list on the label the intended end-use(s) of formulated products produced from the manufacturing-use product; and

4. The applicant for registration of manufacturing-use products complies with all other terms and conditions specified in this Standard and hereby offers and agrees to pay compensation to other persons, with regard to the approval of this application, to the extent required by 3(c)(1)(d) and 3(c)(2)(d) of the Federal Insecticide, Fungicide, and Rodenticide Act [FIFRA], as amended, 7 U.S.C. 136(c)(1)(d) and 136(c)(2)(d).

C. Acceptable Ranges and Limits

1. Product Composition Standards

To be covered under this Standard, all technical and formulation intermediate products must contain Aspon® [O,O,O,O-Tetrapropyl dithiopyrophosphate] as an active ingredient. The Agency will consider for registration manufacturing-use products which contain any percentage of active ingredient. In addition, currently registered and proposed manufacturing-use products must agree to submit or cite the information on product composition identified as data gaps in Section I.D of this document.

Standards have not yet been set for contaminants and inerts in manufacturing-use Aspon® products. When standards are set for any contaminants or inerts in manufacturing-use Aspon® products, manufacturing-use products must comply with those standards.

2. Acute Toxicity Limits

The Agency will grant registration to manufacturing-use Aspon® products which have Toxicity Category I through IV ratings for any of the following acute effects:

1) Acute Oral Toxicity;

2) Acute Dermal Toxicity;

3) Acute Inhalation Toxicity;

4) Primary Eye Irritation; and

5) Primary Dermal Irritation.

3. Use Patterns

To be covered under this Standard, manufacturing-use (i.e., technical and formulation intermediate) products must carry label directions permitting further formulation into end-use pesticides which are intended only for outdoor, non-food, domestic or non-domestic use. Directions for formulation into products intended for other end-uses must be supported by appropriate data and a petition to amend the Standard to permit the extended uses.

D. Data Gaps

To be covered under this Standard, applicants for registration or re-registration of technical and formulation intermediate products must agree to cite or submit the following information on the composition and toxicity of each proposed product. After each data gap is listed the section in the Proposed Guidelines which describes that type of data and when it is required [43 FR, No. 132, 29696 of July 10, 1978; and 43 FR, No. 163, 37336 of August 22, 1978].

| | Guidelines Section |
|---|---|
| Product Chemistry | |
| For Both Technical and Formulation Intermediate | |
| 1) Product Identity | 163.61-3(a) |
| 2) Disclosure of Ingredients | 163.61-3(c) |
| 3) Description of Manufacturing Process | 163.61-4 |
| 4) Formation of Unintentional Ingredients | 163.61-5 |
| 5) Declaration of Limits | 163.61-6(a) |
| 6) Certification of Limits | 163.61-6(b) |
| 7) Analytical Methods | 163.61-7(a) |
| 8) Analytical Results | 163.61-7(b)(1) |
| For Technical | |
| 9) Color | 163.61-8(c)(1) |
| 10) Odor | 163.61-8(c)(2) |
| 11) Melting Point | 163.61-8(c)(3) |
| 12) Solubility (in quantitative terms) | 163.61-8(c)(4) |
| 13) Stability | 163.61-8(c)(5) |
| 14) Octanol/Water Partition Coefficient | 163.61-8(c)(6) |
| 15) Physical State | 163.61-8(c)(7) |
| 16) Density or Specific Gravity | 163.61-8(c)(8) |
| 17) Boiling Point | 163.61-8(c)(9) |
| 18) Vapor Pressure | 163.61-8(c)(10) |
| 19) pH | 163.61-8(c)(11) |
| For Formulation Intermediate | |
| 20) Density or Specific Gravity | 163.61-8(c)(8) |
| 21) Storage Stability | 163.61-8(c)(12) |
| 22) Flammability | 163.61-8(c)(13) |
| 23) Oxidizing or Reducing Action | 163.61-8(c)(14) |
| 24) Explosiveness | 163.61-8(c)(15) |
| 25) Corrosion Characteristics | 163.61-8(c)(18) |
| *Toxicology | |
| 1) Acute Oral Toxicity Study | 163.81-1 |
| 2) Acute Dermal Toxicity Study | 163.81-2 |
| 3) Acute Inhalation Toxicity Study | 163.81-3 |
| 4) Primary Eye Irritation Study | 163.81-4(c) |
| OR | |
| Data on pH of the Product | 163.81-4(b) |
| 5) Primary Dermal Irritation Study | 163.81-5 |
| 6) Dermal Sensitization Study | 163.81-6 |

* A demonstration that a manufacturing-use Aspon® product has a composition substantially similar to a manufacturing-use product for which the Agency already has acceptable acute toxicity data will satisfy acute toxicity data requirements for the former product. Both active and inert ingredients will be considered in making determinations of similarity.

To be covered under this Standard, applicants for registration or re-registration of technical and formulation intermediate products which are labeled for formulation into products intended for outdoor, non-food, non-domestic or domestic uses must agree to submit or cite all of the information required above, as well as the following information:

Non-Domestic or Domestic Use

| | Guidelines Section |
|---|---|
| Environmental Fate | |
| 1) Hydrolysis | 163.62-7(b) |
| 2) Photolysis (in water) | 163.62-7(c) |
| 3) Aerobic Soil Metabolism | 163.62-8(b) |
| 4) Microbial Metabolism | 163.62-8(f)(2) |
| 5) Activated Sludge Metabolism | 163.62-8(g) |
| 6) Leaching | 163.62-9(b) |
| 7) Adsorption/Desorption | 163.62-9(d) |
| 8) Field Dissipation study on representative emulsifiable concentrate and granular formulations | 163.62-10 |
| 9) Fish Accumulation | 163.62-11(d) |
| Toxicology | |
| 1) Teratogenicity Study | 163.83-3 |
| 2) Acute Delayed Neurotoxicity | 163.81-7 |
| Ecological Effects | |
| 1) Microbial Metabolism | 163.62-8(f)(3) |
| 2) The avian acute oral LD-50 for one species of waterfowl (preferably the mallard) or one species of upland game bird (preferably the bobwhite, other native quail, or the ring-necked pheasant) | 163.71-1 |
| 3) A 48-hour LC-50 (or EC-50) for one species of aquatic invertebrate (preferably Daphnia magna) | 163.72-2 |

E. Required Labeling

1. Product Chemistry

The ingredient statement will list the active ingredient as: O,O,O,O-Tetrapropyl dithiopyrophosphate. In all cases,

the percentage by weight of active ingredient and inerts must equal 100%.

Active Ingredient:
O,O,O,O,-Tetrapropyl dithiopyrophosphate..... %
Inert Ingredients..... %
Total..... 100%

2. Human Hazard - Precautionary Labeling

The hazard warnings and first aid statements on all manufacturing-use product labels must correspond to the Toxicity Category assigned to that product for each acute effect. Tables 1 and 2 in Appendix A list the required labeling for each acute Toxicity Category (for more detailed information, see 40 CFR 162.10 on labeling requirements).

3. Environmental Hazards

All manufacturing-use product labels must include the following warning:

"This pesticide is toxic to fish. Do not discharge into lakes, streams, ponds, or public water unless in accordance with NPDES permit. For guidance, contact your Regional Office of the EPA."

4. Physical or Chemical Hazards

Manufacturers of the technical chemical may not ship it to formulators in unlined steel containers. In addition, the technical label should include the following warning, for the information of formulators who use the technical product to manufacture end-use products:

"This product is corrosive to steel. Do not transport or store in unlined steel containers."

5. Use Patterns

All manufacturing-use Aspon® products must list on the label the intended end-use(s) of formulated products produced from the manufacturing-use products. All manufacturing-use Aspon® product labels must contain one of the following statements:

1. "For Formulation Into End-use Insecticide Products, Intended Only For Domestic, Non-food, Outdoor Use";

or

2. "For Formulation Into End-use Insecticide Products, Intended Only For Non-domestic, Non-food, Outdoor Use";

or

3. "For Formulation Into End-use Insecticide Products, Intended Only For Domestic or Non-domestic, Non-food, Outdoor Use."

## II. Regulatory Rationale

### A. Regulatory Decision

The Agency has determined that the technical and formulation intermediate Aspon® products described in this Standard can be registered as manufacturing-use pesticides for sale, distribution, and reformulation in the United States. There are no data currently available which suggest that Aspon® meets any of the risk criteria for unreasonable adverse effects, as listed in 40 CFR 162.11(a). In addition, to be covered under this Standard, applicants must agree to submit or cite the data listed in Section I.D of this document.

### B. Acceptable Ranges and Limits

#### 1. Product Composition Standards

The Agency will consider for registration manufacturing-use products which contain any percentage of Aspon® as an active ingredient. Nevertheless, given current manufacturing-use product grades and formulation methods, the Agency expects that most technical material will range above 90% a.i. and that granular formulation intermediates will range above 25% a.i. Should an applicant desire to register a manufacturing-use product that departs greatly from those currently registered, that applicant should contact the Agency for specific directions on how to accomplish registration.



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2. Acute Toxicity Limits

The Agency will register manufacturing-use Aspon® products which have Toxicity Category I through IV ratings because the use pattern does not result in possible exposure to the general public, and because the pesticide industry can be required to provide safe working conditions (i.e., specialized protective clothing such as respirators) which will mitigate possible hazards from products with high toxicity ratings.

3. Use Patterns

Manufacturing-use pesticides may be used only in the formulation of specific end-use products, because [under the Proposed Guidelines, 163.40-2(c) and (d)] manufacturing-use pesticides are not intended for pesticidal application as registered.

C. Data Gaps

The data which applicants are required to submit or cite in order to obtain (re)registration for manufacturing-use Aspon® are listed in Section I.D of this document.

A field dissipation study on representative emulsifiable concentrate and granular products is required for all manufacturing-use products because they are labeled for formulation into end-use Aspon® products intended for terrestrial use. A teratology study is required for manufacturing-use products labeled for formulation into domestic or non-domestic end-use products because the use

pattern could result in exposure to pregnant women. Other chronic studies, such as oncogenicity, are not currently required because the use pattern is not expected to result in repeated exposure to humans over a significant portion of the human life-span.

D. Required Labeling

Acute toxicity hazard warnings must accurately reflect the product's level of toxicity (products may not be labeled to show either greater or lesser hazard from the product than in fact exists). Because the currently registered 90% a.i. technical product has been determined to be corrosive to steel, technical manufacturers may not ship the technical to formulators in unlined steel containers; in addition, the current label must be modified to include a warning against transportation or storage in unlined steel containers (see Section I.E).

III. Product Chemistry

FIFRA 3(c)(2)(A) requires the Agency to establish guidelines for registering pesticides in the United States. The Agency requires registrants to provide quantitative data on all added ingredients, active and inert, which are equal to or greater than 0.1% of the product by weight.

To establish the composition of products proposed for registration, the Agency requires data and information not only on the manufacturing and formulation processes, but also a discussion on the formation of manufacturing impurities and other product ingredients, intentional and unintentional. Further, to assure that the composition of the product as marketed will not vary from the composition evaluated at the time of registration, applicants are required to submit a statement certifying the upper and lower composition limits for the added ingredients, or upper limits only for some unintentional ingredients. Subpart D suggests specific precision limits for ingredients based on the percentage of ingredient and the standard deviation of the analytic method.

In addition to the data on product composition, the Agency also requires data to establish the physical and chemical properties of both the pesticide active ingredient and its formulations. For example, data are needed concerning the identity and physical state of the active ingredient (e.g., melting and boiling point data, vapor pressure



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and solubility). Data are also required on the properties of the formulated product to establish labeling cautions (e.g., flammability, corrosivity or storage stability). The Agency uses these data to characterize each pesticide and to determine its environmental and health hazards.

DISCIPLINARY REVIEW

Chemistry Profile
Data Gaps
Required Labeling

Chemistry Profile

"Aspon®" is a trade name for O,O,O,O-Tetrapropyl dithiopyrophosphate. The technical material is a straw-to-dark amber liquid with a moderately aromatic odor. It is stable at room temperature, miscible with most organic solvents, and compatible with commonly-used pest control materials. It is corrosive to steel.

Data Gaps

Listed below are Product Chemistry data needed to obtain registration or reregistration for all manufacturing-use Aspon® products. After each data gap is listed the section in the Proposed Guidelines (July 10, 1978, 43 FR, No. 132, 29696) which describes that type of data and when it is required.

| For Both Technical and Formulation Intermediate | Guidelines Section |
|---|---|
| 1) Product Identity | 163.61-3(a) |
| 2) Disclosure of Ingredients | 163.61-3(c) |
| 3) Description of Manufacturing Process | 163.61-4 |
| 4) Formation of Unintentional Ingredients | 163.61-5 |
| 5) Declaration of Limits | 163.61-6(a) |
| 6) Certification of Limits | 163.61-6(b) |
| 7) Analytical Methods | 163.61-7(a) |
| 8) Analytical Results | 163.61-7(b)(1) |

For Technical

9) Color..... 163.61-8(c)(1)
10) Odor..... 163.61-8(c)(2)
11) Melting Point..... 163.61-8(c)(3)
12) Solubility (in quantitative terms)..... 163.61-8(c)(4)
13) Stability..... 163.61-8(c)(5)
14) Octanol/Water Partition Coefficient..... 163.61-8(c)(6)
15) Physical State..... 163.61-8(c)(7)
16) Density or Specific Gravity..... 163.61-8(c)(8)
17) Boiling Point..... 163.61-8(c)(9)
18) Vapor Pressure..... 163.61-8(c)(10)
19) pH..... 163.61-8(c)(11)
20) Flammability..... 163.61-8(c)(13)
21) Explosiveness..... 163.61-8(c)(15)
22) Viscosity..... 163.61-8(c)(17)
23) Corrosion Characteristics..... 163.61-8(c)(18)

For Formulation Intermediate

24) Density or Specific Gravity..... 163.61-8(c)(8)
25) Storage Stability..... 163.61-8(c)(12)
26) Flammability..... 163.61-8(c)(13)
27) Oxidizing or Reducing Action..... 163.61-8(c)(14)
28) Explosiveness..... 163.61-8(c)(15)
29) Corrosion Characteristics..... 163.61-8(c)(18)

Required Labeling

Ingredient Statement: The ingredient statement will list the active ingredient as O,O,O,O-Tetrapropyl dithiopyrophosphate.

Physical Hazard Precautionary Labeling: Since the technical product is corrosive to steel, technical manufacturers may not ship it to formulators in unlined steel containers, and the technical label must carry the following warning:

"This product is corrosive to steel. Do not transport or store in steel containers."

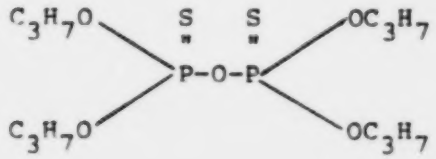
TOPICAL DISCUSSIONS

Corresponding to each of the Topical Discussions listed below is the number of the section in the 'Proposed Guidelines for Registering Pesticides' of July 10, 1978 (43 FR, No. 132, 29696), which explains the minimum Product Chemistry data needed in order to obtain registration or reregistration for manufacturing-use Aspon® products.

| | Guidelines Section |
|---|---|
| Chemical Identity..... | 163.61-3 |
| Manufacturing Processes..... | 163.61-4 |
| Formation of Unintentional Ingredients... | 163.61-5 |
| Ingredients in Pesticide Products..... | 163.61-6 |
| Product Analytical Methods and Data..... | 163.61-7 |
| Physical/Chemical Properties..... | 163.61-8 |

Chemical Identity

At present, there is no acceptable common name for the insecticide, O,O,O,O-Tetrapropyl dithiopyrophosphate.



Other names, as listed on Chemline (March 1980) are as follow:

Thiopyrophosphoric acid [((HO)2PS)2O], tetrapropyl ester (8CI)

Thiodiphosphoric acid [((HO)2P(S))2O], tetrapropyl ester (9CI)

NPD

Tetra-n-propyl dithionopyrophosphate

Tetra-n-propyl dithiopyrophosphate

Propyl thiopyrophosphate [((PrO)2P(S))2O]

Other structural identifiers are:

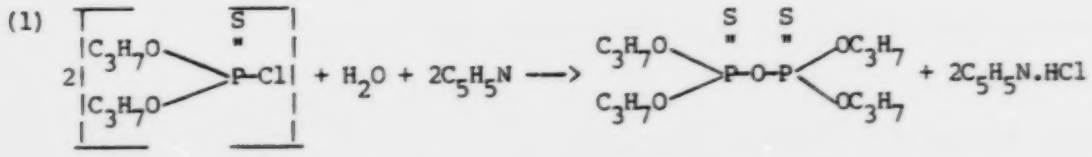
CAS Registry No. 3244-90-4

MF $C_{12}H_{28}O_5P_2S_2$

Mol. Wt. 378.43

Manufacturing Process

Although details of the present manufacturing process are not available, the published literature (Sittig, 1971, MRDI GS0019-002; Sittig, 1977, MRID GS0019-003), as well as the applicable U.S. patent No. 2,663,722 (1953, MRID GS0019-006) indicate the following reactions occur:

(1) 

Only catalytic amounts of pyridine are needed in the presence of an inorganic base. The pyridine hydrochloride immediately reacts with the inorganic base present to regenerate pyridine and water which then further react with the dipropyl chlorothionophosphate:

(2) $2C_5H_5N.HCl + Na_2CO_3 \longrightarrow 2C_5H_5N + H_2O + CO_2 + 2NaCl$

The manufacturing processes are not sufficiently detailed to satisfy Proposed Guidelines requirements and may not even be relevant unless the manufacturer actually uses them.

Formation of Unintentional Ingredients

There is no information available to the Agency on the formation of unintentional ingredients during the manufacture of Aspon® products.

Ingredients in Pesticide Products

For all Aspon® products, the Agency requires a listing of the upper and lower limits established (by the producer or formulator) for each active ingredient, and the upper limit for each impurity, reaction product, and degradation product which is known to be present or which might reasonably be identified.

(a) manufacturing-use preparation: the only currently registered technical product contains a minimum of 90.00% active ingredient (a.i.).

(b) formulation intermediate: the only currently registered formulation intermediate (25-G) contains 25.00% a.i.

Product Analytical Methods and Data

Stauffer (1970, MRDI GS0019-005) and Ja et al. (1966, MRID GS0019-001) identify two methods, infrared (IR) and thin-layer chromatographic (TLC)-colorimetric, for the analysis of technical Aspon®. The IR method is included in the EPA manual of chemical methods for pesticides (EPA, 1976, MRID GS0019-015). (The high-resolution nuclear magnetic resonance (NMR) spectra of analytical-grade Aspon®, as a structural identification aid and reference source, is available from the literature [Keith et al., 1968, MRID 005004395]).

Physical/Chemical Properties

Color: The technical material is a straw-to-dark amber color (Stauffer, 1968, MRID GS0019-004).

Odor: The technical material has a moderately aromatic odor (Stauffer, 1968, MRID GS0019-004).

Melting Point: The melting point of the technical material is below -40°F (given as the freezing point) [Stauffer, 1968, MRID GS0019-004].

Solubility: The solubility of the technical material is 0.16% in water at room temperature (Stauffer, 1968, MRID GS0019-004) and soluble with difficulty in light petroleum (Martin and Worthing, 1977, MRID GS0019-017). It is completely miscible with all common organic solvents (Stauffer, 1968, MRID GS0019-004).

Stability: The technical material is stable with insignificant hydrolysis in water at room temperature and stable for at least 24 hours at 100°C (Stauffer, 1968, MRID GS0019-004); it is compatible with commonly-used pest control materials (Spencer, 1973, MRID GS0019-018).

Octanol/Water Partition Coefficient: No data are available on the technical material.

Physical State: The technical material is in liquid form. The formulation intermediate is in granular form.

Density or Specific Gravity: The technical material's specific gravity is 1.119 to 1.123 at 68/68°F [Stauffer, 1968, MRID GS0019-004]. No data are available on the formulation intermediate.

Boiling Point: The boiling point for the technical material is 104°C at 0.01 mm Hg (Martin and Worthing,

1977, MRID GS0019-017) and 148°C at 2 mm Hg (Spencer,1973, MRID GS0019-018).

Vapor Pressure: No data are available on the technical product.

pH: No data are available on the technical product.

Storage Stability: No data are available on the formulation intermediate.

Flammability: The technical material's flash point [open cup] is 300°F [Stauffer, 1968, MRID GS0019-004]. No data are available on the formulation intermediate.

Oxidizing or Reducing Action: No data are available on the formulation intermediate.

Explosiveness: The technical material decomposes [without explosive hazard] at 300°F [Stauffer, 1968, MRID GS0019-004]. No data are available on the formulation intermediate.

Viscosity: The technical material's viscosity is 12.5 cp at 70°F [Stauffer, 1968, MRID GS0019-004].

Corrosion Characteristics: The technical material may cause discoloration and physical changes on prolonged contact with metal; it is corrosive to steel (Martin and Worthing, 1977, MRID GS0019-017). No data are available on the formulation intermediate.

BIBLIOGRAPHY


| MRID | CITATION |
|---|---|
| | Chemline, Chemical Information on Line [Data base]. Bethesda, Md: National Library of Medicine. March 1980. |
| GS0019-015 | EPA. 1976. EPA manual of chemical methods for pesticides and devices. AOAC, Arlington, Virginia. |
| GS0019-001 | Ja, W.; Smith W.J.; Below, J.F. 1966. The analysis of technical Aspon, Richmond Report No. RR-66-35. Stauffer Chemical Co., New York, N.Y. |
| 00500 4395 | Keith, L.H.; Garrison, A.W.; Alford, A.L. 1968. The high resolution NMR spectra of pesticides. I. organophosphorus pesticides. J. Assoc. Off. Anal. Chem. 51(5):1063-1094. |
| GS0019-017 | Martin, H.; Worthing, C.R., eds. 1977. Pesticide index: basic information on the chemicals used as active components of pesticides. 5th ed. British Crop Protection Council, Worcestershire, England. |
| 00500 1354 | McMahon, B.; Burke, J.A. 1978. Analytical behavior data for chemicals determined using AOAC multiresidue methodology for pesticide residues in foods. J. Assoc. Off. Anal. Chem. 61:640-652. |
| 00500 2074 | Ruzicka, J.H.; Thomson, J.; Wheals, B.B.; Wood, N.F. 1968. The application of gel chromatography to the separation of pesticides. Part I. Organophosphorus pesticides. J. Chromatog. 34(1):14-20. |
| GS0019-002 | Sittig, M. 1971. Agricultural chemicals manufacture. Noyes Data Corp., Park Ridge, N.J. |
| GS0019-003 | Sittig, M. 1977. Pesticides process encyclopedia. Noyes Data Corp., Park Ridge, N.J. |
| GS0019-018 | Spencer, E.Y. 1973. Guide to the chemicals used in crop protection. 6th ed. Canada Dept. of Agriculture, Ontario, Canada. |
| GS0019-004 | Stauffer Chemical Co. 1968. Aspon insecticide, technical information bulletin. New York, N.Y. |
| GS0019-005 | Stauffer Chemical Co. 1970. Infrared procedure to determine the assay of Aspon, method no. MPO 25-3. (Unpublished). New York, N.Y. |
| 00500 4479 | Toy, A.D.F. 1951. Tetraethyl dithionopyrophosphate and related tetraalkyl dithionopyrophosphates. J. Am. Chem. Soc. 73:4670-4674. |
| GS0019-006 | U.S. Patent No. 2,663,722. 1953. Method of preparing tetraalkyl dithionopyrophosphates. |

IV. Environmental Fate

DISCIPLINARY REVIEW

Environmental Fate Profile
Data Gaps

Environmental Fate Profile

There are no data currently available on the environmental fate of Aspon®.

Data Gaps

Listed below are the Environmental Fate data needed to obtain registration or re-registration for manufacturing-use Aspon® products. After each data gap is listed the section in the Proposed Guidelines of July 10, 1978 (43 FR, No. 132 29696) which describes that type of data and when it is required.

| | Guidelines Section |
|---|---|
| 1) Hydrolysis | 163.62-7(b) |
| 2) Photolysis (in water) | 163.62-7(c) |
| 3) Aerobic Soil Metabolism | 163.62-8(b) |
| 4) Microbial Metabolism | 163.62-8(f)(2) |
| 5) Activated Sludge Metabolism | 163.62-8(g) |
| 6) Leaching | 163.62-9(b) |
| 7) Adsorption/Desorption | 163.62-9(d) |
| 8) Field Dissipation study on representative emulsifiable concentrate and granular formulations | 163.62-10 |
| 9) Fish Accumulation | 163.62-11(d) |



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V. Toxicology

DISCIPLINARY REVIEW

Toxicology Profile
Data Gaps
Required Labeling

Toxicology Profile

No data are available on technical or formulation intermediate Aspon®. Potential acute, subacute, or chronic effects in humans, therefore, cannot be assessed. Tests required to support the registration of the technical and formulation intermediate products are listed in the section of this chapter on Data Gaps.

Data Gaps

Listed below are the Toxicology data which must be submitted or cited to obtain registration or re-registration for manufacturing-use Aspon® products which must be filled for each product.* After each data gap is listed the Section in the Proposed Guidelines of August 22, 1978 (43 FR, No. 163, 37336) which describes that type of data and when it is required.

| | Guidelines Section |
|---|---|
| 1) Acute Oral Toxicity Study..... | 163.81-1 |
| 2) Acute Dermal Toxicity Study..... | 163.81-2 |
| 3) Acute Inhalation Toxicity Study... | 163.81-3 |
| 4) Primary Eye Irritation Study..... | 163.81-4(c) |
| OR | |
| Data on pH of the Product..... | 163.81-4(b) |
| 5) Primary Dermal Irritation Study... | 163.81-5 |
| 6) Dermal Sensitization Study..... | 163.81-6 |

* A demonstration that a manufacturing-use Aspon® product has a composition substantially similar to a manufacturing-use product for which the Agency already has acceptable acute toxicity data will satisfy the acute toxicity data requirements for the former product. Both active and inert ingredients will be considered in making determinations of similarity.



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Applicants for registration or re-registration of technical and formulation intermediate products which are formulated into products intended for outdoor, non-food, non-domestic or domestic use must also agree to submit or cite the following information:

Non-Domestic or Domestic Use

| | Guidelines Section |
|---|---|
| 1) Teratogenicity Study | 163.83-3 |
| 2) Acute Delayed Neurotoxicity | 163.81-7 |

Required Labeling

Product-specific acute toxicity precautionary labeling is required. Acceptable categories of acute toxicity, and the corresponding required precautionary labeling statements, appear in Appendix A to this document.

TOPICAL DISCUSSIONS

Corresponding to each of the Topical Discussions listed below is the number of the section in the 'Proposed Guidelines' of August 22, 1978 (43 FR, No. 163, 37336) which explains the minimum Toxicology data needed in order to obtain registration or reregistration for manufacturing-use Aspon® products.

| | Guidelines Sections |
|---|---|
| Acute Effects | 163.81-1, -2, -3, and -7 |
| Local Irritation | 163.81-4 and -5 |
| Sensitization | 163.81-6 |
| Subchronic 21-Day Dermal | 163.82-2 |
| Subchronic Neurotoxicity | 163.82-5 |
| Teratology | 163.83-3 |
| Mutagenicity | 163.84-1 thru -4 |

## Acute Effects

### Acute Oral Toxicity

The minimum data requirement for testing acute oral toxicity (LD-50) is one test on each technical and formulation intermediate product, preferably using the laboratory rat. No data are available for assessing the acute oral LD-50 toxicity of either the technical or the formulation intermediate chemicals.

### Acute Dermal Toxicity

The minimum data requirement for testing acute dermal toxicity (LD-50) is one test, preferably using the albino rabbit, for each technical and formulation intermediate product. This test should be conducted on both intact and abraded skin. No data are available for assessing the acute dermal LD-50 of either the technical or the formulation intermediate chemicals.

### Acute Inhalation Toxicity

The minimum data requirement for testing acute inhalation toxicity (LC-50) is one test for each technical and formulation intermediate product, preferably using the laboratory rat. No data are available for assessing the acute inhalation LC-50 of either the technical or the formulation intermediate chemicals.

### Acute Delayed Neurotoxicity

Data are required on the technical material if the active ingredient, or any of its metabolites, degradation

products, or impurities, cause esterase depression or are structurally related to a substance that induces delayed neurotoxicity.

Aspon® is an organophosphate. Organophosphorus pesticides must be tested for acute delayed neurotoxicity. The preferred species for testing is the female domestic chicken (hen).

No data are available for assessing the acute delayed neurotoxicity of the technical chemical.

Local Irritation

Primary Eye Irritation

The minimum data requirement for testing primary eye irritation is one test for each technical and formulation intermediate product, conducted on a mammal, preferably the albino rabbit. Data which demonstrate that the test substance has a pH of 1-3 or 12-14 should be submitted instead of data from a primary eye irritation test. For all regulatory purposes, the Agency will assume that substances with the above pH values or which cause Category I skin effects are corrosive (i.e., have a Toxicity Category I rating). No data are available for assessing the primary eye irritation potential of either the technical or formulation intermediate chemicals.

Primary Dermal Irritation

The minimum data requirement for testing primary dermal irritation is one test for each technical and

formulation intermediate product, conducted on a mammal, preferably the albino rabbit. No data are available for assessing the primary dermal irritation potential of either the technical or the formulation intermediate chemicals.

Dermal Sensitization

The minimum data requirement for dermal sensitization is an intradermal test on all manufacturing-use products, preferably using the albino guinea pig. These data are required if repeated human skin contact, under the conditions of use, is expected. No data are available for assessing the dermal sensitization of the technical or formulation intermediate chemicals.

Subchronic 21-Day Dermal

This testing may be required on the technical material, depending on data to be submitted on the persistence of Aspon® as applied under use directions for end-use Aspon® products.

Subchronic Neurotoxicity

This testing may be required on the technical material, depending on results of the acute delayed neurotoxicity studies required in this chapter.

Teratology

The minimum data requirement for teratology is a test on the technical material in two mammalian species. This test is required to support the registration of manufacturing-use

products when their pesticidal end-use may reasonably be expected to result in significant exposure to human females. No data are available for assessing the teratology of the technical product.

Mutagenicity

The following studies represent only the minimum requirements for data on the potential heritable effects of Aspon®:

1. A mammalian *in vitro* point mutation test;
2. A sensitive sub-mammalian point mutation test (bacteria, fungi, insect);
3. A primary DNA damage test (i.e., sister chromatid exchange or unscheduled DNA synthesis);
4. A mammalian *in vitro* cytogenetics test. If this test suggests a positive result, a dominant lethal or heritable translocation test may be required.

After results from these test systems and other toxicology disciplines have been considered, additional testing may be required to further characterize or quantify the potential genetic risks.

Although the Agency's mutagenic testing requirements are not final, the standards for these tests should be based on the principles set forth therein (FR 43, No. 163, Tuesday, August 22, 1978). Protocols and choices of test systems should be accompanied by a scientific rationale. Substitutions of test systems for those listed above will be considered after discussion with the Agency.

These requirements should be considered an interim guide and not final Agency policy. However, the Agency does consider the above testing scheme to be a reasonable minimum requirement.

No data are available for assessing the mutagenicity of the technical product, but testing may be required when the Agency's Guidelines on mutagenicity testing are completed.

VI. Residue Chemistry

Use of Aspon® is not likely to result directly in residues in human food and animal feed items because it has not been registered for use on food or feed crops. There are no residue data requirements for non-food uses of Aspon®.



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VII. Ecological Effects

DISCIPLINARY REVIEW

Ecological Effects Profile
Data Gaps
Required Labeling

## Ecological Effects Profile

From the available studies, it is apparent that the technical material is very highly toxic to aquatic organisms, particularly fish. The technical was shown to be practically non-toxic to birds in dietary tests.

## Data Gaps

Listed below are the Ecological Effects data which must be submitted or cited to obtain registration or re-registration for manufacturing-use Aspon® products. After each data gap is listed the section in the Proposed Guidelines of July 10, 1978 (43 FR, No. 132, 29696) which describes that type of data and when it is required.

| | Guidelines Section |
|---|---|
| 1) Microbial Metabolism..... | 163.62-8(f)(3) |
| 2) The avian acute oral LD-50 for one species of waterfowl (preferably the mallard) or one species of upland game bird (preferably the bobwhite, other native quail, or the ring-necked pheasant)..... | 163.71-1 |
| 3) A 48-hour LC-50 (or EC-50) for one species of aquatic invertebrate (preferably Daphnia magna).. | 163.72-2 |

## Required Labeling

All technical and formulation intermediate products intended for shipment must bear the warning: "This pesticide is toxic to fish. Do not discharge into lakes, streams, ponds, or public water unless in accordance with NPDES permit. For guidance, contact your Regional Office of the EPA."



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TOPICAL DISCUSSIONS

Corresponding to each of the Topical Discussions listed below is the number of the section in the 'Proposed Guidelines for Registering Pesticides' of July 10, 1978 (43 FR, No. 132, 29696), which explains the minimum Ecological Effects data needed in order to obtain registration or reregistration for manufacturing-use Aspon® products.

| | Guidelines Sections |
|---|---|
| Microbes | 163.62-8(f)(3) |
| Birds | 163.71-1 and .71-2 |
| Aquatic Invertebrates | 163.72-2 |
| Fish | 163.72-1 |

Microbes

Data on the effects of pesticides on microbes are required to support the registration of manufacturing-use products labeled for formulation into end-use products intended for terrestrial, noncrop uses. There are no microbial data available on Aspon®.

Birds

A determination of the single-dose, oral $LD_{50}$ for one bird species is required to support the registration of every manufacturing-use product. There are no avian $LD_{50}$ data available on Aspon®.

A determination of the avian subacute dietary $LC_{50}$ (5-day dietary exposure) is required to support the registration of all manufacturing-use products. Acceptable data are available on the effects of Aspon® in the diet of several species [see Table 3]. These data indicate that Aspon® is

practically non-toxic, subacutely, to upland game birds and wild waterfowl.

Table 3. Subacute Dietary Toxicity of Aspon® to Birds

| Species | Formulation | LC-50 (ppm) | Reference |
|---|---|---|---|
| Mallard duck | 93% Technical | 4353 | Joiner, 1975, MRID 000004830 |
| Bobwhite quail | 93% Technical | 8414 | Fink and Reno, 1976, MRID 000004831 |
| Ring-necked pheasant | 95% Technical | >5000 | Hill et al., 1975, MRID GS0019-010 |
| Mallard duck | 95% Technical | >5000 | MRID GS0019-010 |
| Japanese quail | 95% Technical | >5000 | MRID GS0019-010 |

A decision to require chronic toxicity data (reproductive or simulated and actual field tests), however, will depend upon the results of studies on persistence, degradation rates, and accumulation.

Aquatic Invertebrates

A determination of the 48-hour $EC_{50}$ or $LC_{50}$ for an aquatic invertebrate species is required to support the registration of all manufacturing-use products. There are no data available on Aspon®.

The decision to require life-cycle or other tests on aquatic invertebrates will depend upon the results of studies on persistence, degradation rates, and accumulation.

Freshwater Fish

The minimum data required for establishing the acute toxicity of Aspon® in fish is a determination of the 96-hour $LC_{50}$ both for one coldwater fish species (preferably rainbow trout) and for one warmwater fish species (preferably bluegill). Acceptable data are available on the acute toxicity of Aspon® to fish in several EPA tests which studied its effects on coldwater as well as warmwater fish. Based on these findings, which are summarized in Table 4, Aspon® can be considered to be very highly toxic to coldwater and warmwater fish species.

Table 4. Acute Toxicity of Technical Aspon® to Freshwater Fish

| Species | Formulation | LC-50 (ppm) | Reference |
|---|---|---|---|
| Rainbow Trout | 90% (Tech.) | 0.07 | EPA, 1975, MRID GS0019-007 |
| Rainbow Trout | 93% (Tech.) | 0.1 | EPA, 1976, MRID GS0019-008 |
| Bluegill | 90% (Tech.) | 0.1 | EPA, 1976, MRID GS0019-009 |

Due to the highly toxic nature of Aspon® with respect to coldwater and warmwater fish, further testing (i.e., embryo-larvae and life-cycle tests [Proposed Guidelines Section 163.72-4]) will depend upon the results of studies on persistence, degradation rates, and accumulation.

BIBLIOGRAPHY


| MRID | CITATION |
|---|---|
| GS0019-007 | EPA. 1975. Report on the toxicity of technical Aspon to rainbow trout. (U.S. EPA, Chemical and Biological Investigations Branch, Beltsville, Maryland, Static jar test No. 913, unpublished report.) |
| GS0019-008 | EPA. 1976. Report on the toxicity of Aspon technical to rainbow trout. (U.S. EPA, Chemical and Biological Investigations Branch, Beltsville, Maryland, Static jar test No. 932, unpublished.) |
| GS0019-009 | EPA. 1976. Report on the toxicity of Aspon Technical to bluegill sunfish. (U.S. EPA, Chemical and Biological Investigations Branch, Beltsville, Maryland, Static jar test No. 998, 7/14/76, unpublished report.) |
| 00000483l | Fink, R.; Reno, F.E. 1976. Final report: eight-day dietary LC-50 — bobwhite quail: project no. 132-129. (Unpublished study received March 8, 1976 under 476-2163; prepared by Hazleton Laboratories America, Inc. in cooperation with Maryland Dept. of Agriculture, Div. of Inspection and Regulation, submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:225231-A). |
| GS0019-010 | Hill, E.F.; Heath, R.G.; Spann, J.W.; Williams, J.D. 1975. Lethal dietary toxicities of environmental pollutants to birds. Special Scientific Report--Wildlife No. 191. U.S. Fish and Wildlife Service, Washington, D.C. |
| 00000483O | Joiner, R.L. 1975. Safety evaluation of Aspon Technical by a five-day feeding test in mallard ducks: T-5397. (Unpublished study received June 26, 1975 under 476-2163; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:223289-A). |

## EMULSIFIABLE CONCENTRATE ASPON®

### I. Regulatory Position

#### A. Regulatory Decision

The Agency has reviewed all data available to it. Although incomplete, these data indicate that emulsifiable concentrate (EC) Aspon® is suitable for registration because it does not meet or exceed the risk criteria leading to a Rebuttable Presumption Against Registration [Chapter 40, Section 162.11(a) of the Code of Federal Regulations]. Data gaps have been identified; when these data are supplied, the Agency will again review the registration status of this compound.

The Agency has determined that EC Aspon® does not appear to cause an unreasonable adverse effect with proper label directions and precautions. Those EC products currently registered may be reregistered subject to the conditions imposed for data requirements, and new products may also be registered under the terms of this Standard.

#### B. Criteria for Registration Under the Standard

To be registered under this Standard, EC formulations of Aspon® must meet the following conditions:

1. The EC product contains Aspon® as an active ingredient [if an unregistered source of Aspon® is used in formulating, then the data outlined under Section 162.18-2(c)(d)(1)(iii) will be required];



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2. The EC Aspon® product is within the acute toxicity limits for restricted or general use and bears the required labeling;

3. The EC Aspon® product is within acceptable ranges for use patterns and application methods; and

4. The applicant for registration of EC products complies with all other terms and conditions specified in this Standard and hereby offers and agrees to pay compensation to other persons, with regard to the approval of this application, to the extent required by 3(c)(1)(d) and 3(c)(2)(d) of the Federal Insecticide, Fungicide, and Rodenticide Act [FIFRA], as amended, 7 U.S.C. 136(c)(1)(d) and 136(c)(2)(d).

C. Acceptable Ranges and Limits

1. Product Composition Standards

To be covered under this Standard, all EC products must contain Aspon® [0,0,0,0-Tetrapropyl dithiopyrophosphate] as an active ingredient. The Agency will consider for registration EC products which contain any percentage of active ingredient. In addition, currently registered and proposed EC products must agree to submit or cite the information on product composition identified as data gaps in Section I.D of this document.

Standards have not yet been set for contaminants and inerts in EC Aspon® products. When standards are set for

any contaminants or inerts in EC Aspon® products, EC end-use products must comply with those standards.

2. Acute Toxicity Limits

a. Restricted Use

The Agency will grant registration to EC Aspon® products as restricted pesticides (i.e., for retail sale to and application only by Certified Applicators or persons under their direct supervision) for non-food, outdoor use which have a Toxicity Category I rating for any of the following acute effects:

1) Acute Oral Toxicity;

2) Acute Dermal Toxicity;

3) Acute Inhalation Toxicity;

4) Primary Eye Irritation; and

5) Primary Dermal Irritation.

b. Non-Domestic Use

The Agency will grant registration to EC Aspon® products intended for non-domestic, non-food, outdoor use which have a Toxicity Category II rating for any of the following acute effects:

1) Acute Oral Toxicity;

2) Acute Dermal Toxicity; or

3) Acute Inhalation Toxicity;

The Agency will grant registration to EC Aspon® products intended for non-domestic, non-food, outdoor use which have a Toxicity Category I or II rating for either of

the following acute effects:

1) Primary Eye Irritation; and

2) Primary Dermal Irritation.

c. Domestic Use

The Agency will grant registration to EC Aspon® products intended for domestic, non-food, outdoor use which have a Toxicity Category III or IV rating for any of the following acute effects:

1) Acute Oral Toxicity;

2) Acute Dermal Toxicity;

3) Acute Inhalation Toxicity;

The Agency will grant registration to EC Aspon® products intended for domestic, non-food, outdoor use which have a Toxicity Category I through IV rating for either of the following acute effects:

1) Primary Eye Irritation; and

2) Primary Dermal Irritation.

3. Use Patterns and Application Methods

To be covered this Standard, EC products may be used only as an insecticide on home lawns or ornamental turf. Application may not be made aerially or by air blast methods. Currently registered EC products must retain present recommendations for dosage rates on the labels. Applicants who wish to increase the dosage recommendations on currently registered products, or who wish to register new products with higher dosage recommendations than those currently

registered, may be required to submit additional supporting data.

D. Data Gaps

To be covered under this Standard, applicants for registration or reregistration of EC Aspon® products must agree to submit or cite the following information on the composition and toxicity of each proposed product. After each data gap is listed the section in the Proposed Guidelines which describes that type of data and when it is required [43 FR, No. 132, 29696 of July 10, 1978; and 43 FR, No. 163, 37336 of August 22, 1978].

| | Guidelines Section |
|---|---|
| Product Chemistry | |
| 1) Product Identity | 163.61-3(a) |
| 2) Disclosure of Ingredients | 163.61-3(c) |
| 3) Description of Manufacturing Process | 163.61-4 |
| 4) Formation of Unintentional Ingredients | 163.61-5 |
| 5) Declaration of Limits | 163.61-6(a) |
| 6) Certification of Limits | 163.61-6(b) |
| 7) Analytical Methods | 163.61-7(a) |
| 8) Analytical Results | 163.61-7(b)(1) |
| 9) Color | 163.61-8(c)(1) |
| 10) Odor | 163.61-8(c)(2) |
| 11) Density or Specific Gravity | 163.61-8(c)(8) |
| 12) Storage Stability | 163.61-8(c)(12) |
| 13) Flammability | 163.61-8(c)(13) |
| 14) Oxidizing or Reducing Action | 163.61-8(c)(14) |
| 15) Explosiveness | 163.61-8(c)(15) |
| 16) Miscibility | 163.61-8(c)(16) |
| 17) Viscosity | 163.61-8(c)(17) |
| 18) Corrosion Characteristics | 163.61-8(c)(18) |
| 19) Dielectric Breakdown Voltage | 163.61-8(c)(19) |

| *Toxicology | Guidelines Section |
|---|---|
| ECs Between 12% and 28% a.i. | |
| 1) Acute oral toxicity (rat) on product in upper range (i.e., @ 25% a.i.) | 163.81-1 |
| 2) Acute inhalation (rat) on product in upper range (i.e., @ 25% a.i.) | 163.81-3 |
| ECs Between 65% and 68% a.i. | |
| 1) Acute oral toxicity (rat) | 163.81-1 |
| 2) Acute dermal toxicity (rabbit) | 163.81-2 |
| 3) Acute inhalation (rat) | 163.81-3 |
| 4) Primary eye irritation (rabbit) | 163.81-4(c) |
| OR | |
| Data on pH of the Product | 163.81-4(b) |
| 5) Primary skin irritation (rabbit) | 163.81-5 |
| ECs With Aspon® and Other Active Ingredients | |
| 1) Acute oral toxicity (rat) | 163.81-1 |
| 2) Acute dermal toxicity (rabbit) | 163.81-2 |
| 3) Acute inhalation (rat) | 163.81-3 |
| 4) Primary eye irritation (rabbit) | 163.81-4(c) |
| OR | |
| Data on pH of the Product | 163.81-4(b) |
| 5) Primary skin irritation (rabbit) | 163.81-5 |

E. Required Labeling

1. Product Chemistry

The ingredient statement will list the active ingredient as: O,O,O,O-Tetrapropyl dithiopyrophosphate. In all cases, the percentages by weight of active ingredient and inerts must equal 100%.

* A demonstration that an EC Aspon® product has a composition substantially similar to an EC product for which the Agency already has acceptable acute toxicity data will satisfy acute toxicity data requirements for the former product. Both active and inert ingredients will be considered in making determinations of similarity.

Active Ingredient:
O,O,O,O-Tetrapropyl dithiopyrophosphate..... %
Inert Ingredients..... %
Total..... 100%

If EC products contain petroleum distillates, the statement "Contains petroleum distillates" must appear on the label in close proximity to the ingredient statement.

Active Ingredient:
O,O,O,O-Tetrapropyl dithiopyrophosphate..... %
Inert Ingredients*..... %
Total..... 100%
* Contains Petroleum Distillates

2. Human Hazard - Precautionary Labeling

The hazard warnings and first aid statements on all EC product labels must correspond to the Toxicity Category assigned to that product for each acute effect (see Appendix A). Specifically, all currently registered ECs between 12% and 28% a.i. must carry on the label the acute toxicity hazard warnings and first aid statements required for the following Toxicity Categories:

1) Acute Dermal Toxicity - III

2) Primary Eye Irritation - I

3) Primary Dermal Irritation - II

If the EC Aspon® product has an Acute Oral Toxicity Category IV and contains greater than 10% petroleum distillates, the following first aid statement must appear on the label (see also Table 2, Appendix A):

If swallowed: If the patient is unconscious, maintain breathing and heart rate (CPR:cardiopulmonary

resuscitation). Contact your local Poison Control Center, physician, or hospital immediately. Do Not Induce Vomiting!

If the EC Aspon® product has an Acute Oral Toxicity Category I and contains greater than 10% petroleum distillates, the following first aid statement must appear on the label (see also Table 2, Appendix A):

If swallowed: If the patient is unconscious, maintain breathing and heart rate (CPR:cardiopulmonary resuscitation). Contact your local Poison Control Center, physician, or hospital immediately. If the patient is conscious, induce vomiting (syrup of ipecac; if not available, stimulate the back of the throat with finger). Never give anything by mouth to an unconscious person!

If the EC Aspon® product has an Acute Oral Toxicity Category II or III and contains greater than 10% petroleum distillates, the following first aid statement must appear on the label (see also Table 2, Appendix A):

If swallowed: If the patient is unconscious, maintain breathing and heart rate (CPR:cardiopulmonary resuscitation). Contact your local Poison Control Center, physician, or hospital immediately.

The question of whether vomiting should or should not be induced will be determined on a case-by-case basis based on a review of the toxicity of active ingredients, inert ingredients, and impurities.

3. Environmental Fate

Because the use pattern clearly indicates the possibility of post-application exposure to children and pets, the following warning must appear on all EC labels: "Keep children and pets off treated areas for 48 hours after application and until the grass has completely dried." Other environmental precautions not in conflict with specific parts of this Standard should be retained.

4. Environmental Hazards

All EC products must bear the label warning: "This pesticide is toxic to fish. Do not contaminate water by cleaning of equipment or disposal of wastes."

II. Regulatory Rationale

A. Regulatory Decision

The Agency has determined that the EC Aspon® products described in this Standard can be registered for sale, distribution, and use in the United States. There are no data currently available to the Agency which suggest that Aspon® meets any of the risk criteria for unreasonable adverse effects, as listed in 40 CFR 162.11(a). In addition, to be covered under this Standard, applicants must agree to submit or cite the data listed in Section I.D of this document, and must also meet the standards for use as listed in Section I.C.2 of this document.

B. Acceptable Ranges and Limits

1. Product Composition Standards

The Agency will consider for registration EC products which contain any percentage of Aspon® as an active ingredient as long as the products meet the acute toxicity standards listed in Section I.C.2 for domestic, non-domestic, or restricted use. The Agency considers that the use restrictions and required protective clothing for the several acute toxicity levels will adequately protect humans and the environment from unreasonable adverse effects.

2. Acute Toxicity Limits

a. Restricted Use

The Agency will register EC Aspon® products for restricted, non-food, outdoor use which have a Toxicity



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Category I rating because certified applicators can legitimately be expected to provide the specialized protective clothing (for themselves or those under their supervision) which are required for products with a Toxicity Category I rating.

b. Non-Domestic Use

The Agency will register EC Aspon® products for non-domestic, non-food, outdoor use which have a Toxicity Category II rating for acute oral, dermal, or inhalation toxicity, or which have a Toxicity Category I or II rating for primary eye or dermal irritation because non-domestic users can legitimately be expected to provide the specialized protective clothing (for themselves or their employees) which are required for products with these Toxicity Category ratings. The Agency considers that these restrictions, together with use of the required protective clothing, will adequately protect humans from unreasonable adverse effects.

c. Domestic Use

The Agency will register EC Aspon® products for domestic, non-food, outdoor use which have a Toxicity Category III or IV rating for acute oral, dermal, or inhalation toxicity, or which have a Toxicity Category I through IV rating for primary eye or dermal irritation. EC products intended for domestic use with Toxicity Category I or II ratings for primary eye or dermal irritation must meet the criteria for child resistant packaging [see FR 44(48):13019-

13024, March 9, 1979]. The Agency considers that the economic and aesthetic benefits from Aspon® use outweigh the risks from products with acute Toxicity Category ratings of III or IV, and that the use of child-resistant packaging for products with Toxicity Category I or II ratings for primary eye or dermal irritation will adequately protect humans from unreasonable adverse effects.

3. Use Patterns and Application Methods

EC Aspon® products may be registered for use as an insecticide only on lawns and ornamental turf. EC products may not be used on food crops because the hazard of such uses and of residue ingestion has not been evaluated nor has such an evaluation been requested. Application may not be made aerially or by air blast methods because these two methods can reasonably be expected to result in high exposures to applicators, other persons, or wildlife close to the application site. Currently registered EC products must retain the dosage recommendations on the labels, in the absence of data to support higher rates.

C. Data Gaps

The data on the physical/chemical composition and acute toxicity which applicants are required to submit or cite for EC Aspon® products are listed in Section I.D of this document. These data are required in order to obtain registration for any proposed end-use product.

D. Required Labeling

Acute toxicity hazard warnings must accurately reflect the product's level of toxicity (products may not be labeled to show either greater or lesser hazard from the product than in fact exists). Proper emergency medical treatment of patients who have ingested petroleum distillates is a controversial subject. Two significant risks must be weighted in reaching a decision on whether or not to induce emesis [vomiting] or perform gastric lavage. If vomiting is induced, or gastric lavage is performed, petroleum distillates may be aspirated, possibly resulting in a fatal chemical pneumonitis. However, retaining a highly toxic pesticide in the stomach even for a short period of time may also prove fatal. In reaching a decision on appropriate labeling policy for products, the Agency considers the toxic properties of active ingredients, inerts, and impurities; the Agency also considers that emergency treatment may not be readily available and that first aid will usually be administered by a member of the family or general public who has little or no medical training. In general, therefore, the Agency believes that the best advice is to seek medical help immediately and to keep the patient breathing until medical help is available. The following first aid statement must therefore appear on all labels of EC Aspon® products which contain greater than 10% by weight petroleum distillates:

1. If patient is unconscious, maintain breathing and hearbeat (CPR:cardiopulmonary resuscitation). Contact your local Poison Control Center, hospital, or physician immediately.

In addition to Statement #1, all products which contain greater than 10% by weight petroleum distillates and are in Oral Toxicity Category I must carry the following statement on the label:

. 2. If patient is conscious, induce vomiting (syrup of ipecac; if not available, stimulate back of throat with finger). Never give anything by mouth to an unconscious person!

In addition to Statement #1, all products which contain greater than 10% by weight petroleum distillates and are in Oral Toxicity Category IV must carry the following statement on the label:

3. Do not induce vomiting!

Products in Oral Toxicity Categories II and III will be dealt with on a product-by-product basis at the time of registration; labeling cautions will be based on a review of active ingredient toxicity, inert ingredients, and impurities.

Because the use pattern indicates the possibility of exposure to children and pets, all EC Aspon® products must carry the following warning: "Keep children and pets off treated areas for 48 hours and until grass has completely dried."

III. Product Chemistry

DISCIPLINARY REVIEW

Chemistry Profile
Data Gaps
Required Labeling

Chemistry Profile

"Aspon®" is a trade name for O,O,O,O-tetrapropyl dithiopyrophosphate. No change was reported in the composition of a 15% EC formulation after 13 months at 68 and 100°F. No other data are available on the physical/chemical characteristics of any EC formulation.

Data Gaps

Listed below are the Product Chemistry data needed to obtain registration or re-registration for EC Aspon® products. After each data gap is listed the section in the Proposed Guidelines (July 10, 1978, 43 FR, No. 132, 29696) which describes that type of data and when it is required.

| | Guidelines Section |
|---|---|
| 1) Product Identity | 163.61-3(a) |
| 2) Disclosure of Ingredients | 163.61-3(c) |
| 3) Description of Manufacturing Process | 163.61-4 |
| 4) Formation of Unintentional Ingredients | 163.61-5 |
| 5) Declaration of Limits | 163.61-6(a) |
| 6) Certification of Limits | 163.61-6(b) |
| 7) Analytical Methods | 163.61-7(a) |
| 8) Analytical Results | 163.61-7(b)(1) |
| 9) Color | 163.61-8(c)(1) |
| 10) Odor | 163.61-8(c)(2) |
| 11) Density or Specific Gravity | 163.61-8(c)(8) |
| 12) Storage Stability | 163.61-8(c)(12) |
| 13) Flammability | 163.61-8(c)(13) |
| 14) Oxidizing or Reducing Action | 163.61-8(c)(14) |
| 15) Explosiveness | 163.61-8(c)(15) |
| 16) Miscibility | 163.61-8(c)(16) |
| 17) Viscosity | 163.61-8(c)(17) |
| 18) Corrosion Characteristics | 163.61-8(c)(18) |
| 19) Dielectric Breakdown Voltage | 163.61-8(c)(19) |



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Required Labeling

Ingredient Statement: The ingredient statement will list the active ingredient as O,O,O,O-Tetrapropyl dithiopyrophosphate. If EC products contain petroleum distillates, the statement "Contains petroleum distillates" must appear on the label in close proximity to the ingredient statement.

TOPICAL DISCUSSIONS

Corresponding to each of the Topical Discussions listed below is the number of the section in the 'Proposed Guidelines for Registering Pesticides' of July 10, 1978 (43 FR, No. 132, 29696), which explains the minimum Product Chemistry data needed in order to obtain registration or reregistration for EC Aspon[R] products.

| | Guidelines Section |
|---|---|
| Chemical Identity | 163.61-3 |
| Manufacturing Processes | 163.61-4 |
| Formation of Unintentional Ingredients | 163.61-5 |
| Ingredients in Pesticide Products | 163.61-6 |
| Product Analytical Methods and Data | 163.61-7 |
| Physical/Chemical Properties | 163.61-8 |

Chemical Identity

At present, there is no acceptable common name for the insecticide, O,O,O,O-Tetrapropyl dithiopyrophosphate. For a discussion of other identifiers of this active ingredient, see the Product Chemistry chapter in the section of this document on manufacturing-use products.

Manufacturing Process

The Agency has no information on present-day manufacturing processes for any EC product.

Formation of Unintentional Ingredients

The Agency has no information on the possible formation of unintentional ingredients in any EC product.

Ingredients in Pesticide Products

For all pesticide products, the Agency requires a listing of the upper and lower limits established (by the producer or formulator) for each active ingredient, and the upper limit for each impurity, reaction product, and degradation product which is known to be present or which might reasonably be identified. Currently registered EC products range from 12.10 to 67.64% a.i.

Product Analytical Methods and Data

No methods for analysis of EC products have been submitted or reported.

Physical/Chemical Properties

Color: There are no data available on any EC formulation.

Odor: There are no data available on any EC formulation.

Physical State: EC products are in liquid form.

Density or Specific Gravity: There are no data available on any EC or granular formulation.

Storage Stability: Chevron (1975, MRID 000004843) reports no change in the composition of a 15% EC formulation after 13 months at 68 and 100°F.

Flammability: No data are available on any EC formulation.

Oxidizing or Reducing Action: No data are available on any EC formulation.

Explosiveness: No data are available on any EC formulation.

Miscibility: No data are available on any EC formulation.

Viscosity: No data are available on any EC formulation.

Corrosion Characteristics: No data are available on any EC formulation.

Dielectric Breakdown Voltage: No data are available on any EC formulation.

BIBLIOGRAPHY


| MRID | CITATION |
| --- | --- |
| 00000 4843 | Chevron Chemical Co. 1975. Product research and services: shelf-life test: Ortho Chinch Bug Lawn Spray. (Unpublished study received Dec. 3, 1975 under 239-2445; CDL:228761-A.) |

IV. Environmental Fate

DISCIPLINARY REVIEW

Environmental Fate Profile
Exposure Profile
Required Labeling

Environmental Fate Profile

There are no data currently available on the environmental fate of Aspon®.

Exposure Profile

Because of the lack of environmental fate data for Aspon®, the Agency can make only brief generalizations about the possibility and extent of exposure.

For persons involved in the dilution, mixing, and application of EC products, there is little chance of oral exposure except through accidental ingestion. Aspon® is not registered for use on food or feed crops, so there is very little possibility of dietary exposure to the general public. (Depending on the leaching, mobility, and spray-drift characteristics of the EC products, home use may result in contamination of home garden vegetables.) Dermal and eye exposure may result from the splashing that can occur in the preparation of finished sprays. While the vapors from the ECs depend upon the vapor pressure and the viscosity of the solutions, the spray droplets generated by the application of EC products may result in an inhalation exposure for applicators, homeowners, domestic animals, or wildlife close to the spraying.

Required Labeling

Although there are no data available on the environmental fate of Aspon® from which to determine label precautions, the use pattern (on home lawns) clearly indicates the possibility of post-application exposure to children and pets. The following warning must therefore appear on all EC labels:

"Keep children and pets off treated areas for 48 hours after application and until the grass has completely dried."

V. Toxicology

DISCIPLINARY REVIEW

Toxicology Profile
Toxicology Hazard Assessment
Data Gaps
Required Labeling

Toxicology Profile

The acute dermal toxicity in rabbits (2.0 g/kg) indicates a potentially low acute dermal toxicity in humans for the 13% a.i. EC product tested. No data were available to assess the acute oral or acute inhalation toxicity of any EC product. Data are insufficient to assess the full range of acute toxicity of all EC formulations.

Several eye irritation studies conducted on rabbits showed a wide variety of results (persistent eye irritation and corneal opacity at day 14 to slight eye irritation at 1 hour and no corneal opacity) which indicate a possibly severe eye irritant to humans from the 13-14.2% EC product tested. A study conducted with a 13-14.2% EC on rabbits to assess primary dermal irritation resulted in severe irritation at 72 hours which indicates a potentially severe skin irritant to humans. Sufficient data were not available to totally assess the primary eye irritation or primary dermal irritation of all EC formulations.

Toxicology Hazard Assessment

The 'Exposure Profile' which appears in the Environmental Fate chapter lists the chance of oral exposure to EC products

as small with some (unknown) possibility of dietary exposure from residues on home garden crops. No oral toxicology hazard assessment can be made for any EC product, however, because of the lack of data.

Similarly, although some chance of inhalation exposure to EC products exists, dependant on the vapor pressures and viscosities of the various products, no inhalation toxicology hazard assessment can be made for any EC product because of the lack of data.

Application of EC products can result in dermal exposure to applicators and homeowners, including ocular exposure. In addition, for home uses, children and pets may be exposed to treated lawns. The amount of exposure cannot be determined because of data gaps on the environmental fate of Aspon®. Eye exposure to a 13% a.i. EC product can result in irreversible corneal opacity and severe eye irritation. Although the acute dermal toxicity of the 13% EC tested is low to moderate, dermal exposure can result in primary dermal irritation, including severe irritation or moderate erythema and edema. No toxicology hazard assessment can be made for EC products with a percent a.i. higher than 13% because of the lack of data.

Data Gaps

Listed below are the Toxicology data which must be submitted or cited to obtain registration or re-registration

for EC Aspon® products.* After each data gap is listed the Section in the Proposed Guidelines of August 22, 1978 (43 FR, No. 163, 37336) which describes that type of data and when it is required. The Agency has determined that currently registered EC products between 12% and 28% a.i. are substantially similar in composition, and that EC products between 65% and 68% a.i. are substantially similar in composition. Acute toxicity data available on any one product in either group may be cited in support of the registration of any other product in that group, provided compnesation has been offered for use of these data. Currently registered EC Aspon® products which contain other active ingredients must be tested individually for each acute effect.

| | Guidelines Section |
|---|---|
| ECs Between 12% and 28% a.i. | |
| 1) Acute oral toxicity (rat) on product in upper range (i.e., @ 25% a.i.)..... | 163.81-1 |
| 2) Acute inhalation (rat) on product in upper range (i.e., @ 25% a.i.)..... | 163.81-3 |
| ECs Between 65% and 68% a.i. | |
| 1) Acute oral toxicity (rat).... | 163.81-1 |
| 2) Acute dermal toxicity (rabbit)..... | 163.81-2 |
| 3) Acute inhalation (rat)..... | 163.81-3 |
| 4) Primary eye irritation (rabbit)..... | 163.81-4(c) |
| OR | |
| Data on pH of the Product.... | 163.81-4(b) |
| 5) Primary skin irritation (rabbit)..... | 163.81-5 |

* A demonstration that an EC Aspon® product has a composition substantially similar to an EC product for which the Agency already has acceptable acute toxicity data will satisfy acute toxicity data requirements for the former product. Both active and inert ingredients will be considered in making determinations of similarity.

ECs With Aspon® and Other Active Ingredients

1) Acute oral toxicity (rat).... 163.81-1
2) Acute dermal toxicity (rabbit)..... 163.81-2
3) Acute inhalation (rat)..... 163.81-3
4) Primary eye irritation (rabbit)..... 163.81-4(c)
   OR
   Data on pH of the Product.... 163.81-4(b)
5) Primary skin irritation (rabbit)..... 163.81-5

Required Labeling

Product-specific acute toxicity precautionary labeling is required. Acceptable categories of acute toxicity, and the corresponding required precautionary labeling statements, appear in Appendix A to this document.

If the EC Aspon® product has an Acute Oral Toxicity Category IV and contains greater than 10% by weight petroleum distillates, the following first aid statement must appear on the label (see also Table 2, Appendix A):

> If swallowed: If the patient is unconscious, maintain breathing and heart rate (CPR:cardiopulmonary resuscitation). Contact your local Poison Control Center, physician, or hospital immediately. Do Not Induce Vomiting!

If the EC Aspon® product has an Acute Oral Toxicity Category I and contains greater than 10% by weight petroleum distillates, the following first aid statement must appear on the label (see also Table 2, Appendix A):

> If swallowed: If the patient is unconscious, maintain breathing and heart rate (CPR:cardiopulmonary

resuscitation). Contact your local Poison Control Center, physician, or hospital immediately. If the patient is conscious, induce vomiting (syrup of ipecac; if not available, stimulate the back of the throat with finger). Never give anything by mouth to an unconscious person!

If the EC Aspon® product has an Acute Oral Toxicity Category II or III and contains greater than 10% by weight petroleum distillates, the following first aid statement must appear on the label (see also Table 2, Appendix A):

If swallowed: If the patient is unconscious, maintain breathing and heart rate (CPR:cardiopulmonary resuscitation). Contact your local Poison Control Center, physician, or hospital immediately.

The question of whether vomiting should or should not be induced for products with Acute Oral Toxicity Categories of II and III will be determined on a case-by-case basis based on a review of the toxicity of active ingredients, inert ingredients, and impurities.

TOPICAL DISCUSSIONS

Corresponding to each of the Topical Discussions listed below is the number of the section in the 'Proposed Guidelines' of August 22, 1978 (43 FR, No. 163, 37336) which explains the minimum Toxicology data needed in order to obtain registration or reregistration for EC Aspon® products.

| | Guidelines Sections |
|---|---|
| Acute Effects | 163.81-1, -2, and -3 |
| Local Irritation | 163.81-4 and -5 |

## Acute Effects

### Acute Oral Toxicity

The minimum data requirement for testing acute oral toxicity (LD-50) is one test on a registered product from each group of substantially similar products (see the Data Gaps section in this chapter), preferably using the laboratory rat. No data are available for assessing the acute oral LD-50 of any EC product.

### Acute Dermal Toxicity

The minimum data requirement for testing acute dermal toxicity (LD-50) is one test, preferably using the albino rabbit, for a registered product from each group of substantially similar products (see the Data Gaps section in this chapter). The acute dermal LD-50 for a 13-14.2% EC in male rabbits is greater than 2.0 g/kg (Rittenhouse and Narcisse, 1972, MRID 000004838). Moderate skin irritation was noted but was not persistent at 72 hours. The data are adequate to assign the 13-14.2% EC product tested to Toxicity Category III for acute dermal toxicity. Currently registered products between 12% and 28% should also be assigned to Category III for acute dermal toxicity. No data are available for assessing the acute dermal toxicity of any EC product between 65% and 68% a.i., or any EC product which contains Aspon® plus other active ingredients.

Acute Inhalation Toxicity

The minimum data requirement for testing acute inhalation toxicity (LC-50) is one test for a registered product from each group of substantially similar products (see the Data Gaps section in this chapter), preferably using the laboratory rat. No data are available for assessing the acute inhalation LC-50 of any EC product.

Local Irritation

Primary Eye Irritation

The minimum data requirement for testing primary eye irritation is one test for a registered product from each group of substantially similar products (see the Data Gaps section in this chapter), conducted on a mammal, preferably the albino rabbit. Data which demonstrate that the test substance has a pH of 1-3 or 12-14 should be submitted instead of data from a primary eye irritation test. For all regulatory purposes, the Agency will assume that substances with the above pH values or which cause Category I skin effects are corrosive (i.e., have a Toxicity Category I rating).

Disparate test results were obtained in three adequate tests conducted on rabbits using a 13% EC product. In one study (Narcisse,1972, MRID 000004836), male rabbits were observed for 7 days after applcation of a 13% EC to the eye. Persistent eye irritation was

noted at day 7, the last day of observation. Another study was conducted (Bullock and Narcisse, 1974, MRID 000004835). Male and female rabbits were observed for 14 days after application of a 13% EC product to the eye. Persistent iritis, conjuctival redness, and discharge were noted until day 7; corneal opacity was reported in half the test animals at day 14.

In yet another study (Gregory and Narcisse, 1974, MRID 000004833), female rabbits were observed for 14 days after application of a 13% EC product to the eye. Slight eye irritation was noted at 1 hour. No corneal opacity was noted in any test animal.

The existing data are sufficient to assess the primary eye irritation potential of the 13% EC product tested and to place it in Toxicity Category I, indicating severe eye irritation hazard. Currently registered products between 12% and 28% a.i. should also be assigned to Category I for primary eye irritation. No data are available for assessing the primary eye irritation of any EC product between 65% and 68% a.i., or any EC product which contains Aspon® plus other active ingredients.

Primary Dermal Irritation

The minimum data requirement for testing primary dermal irritation is one test for a registered product from each group of substantially similar products (see

the Data Gaps section in this chapter), conducted on a mammal, preferably the albino rabbit. Narcisse (1972, MRID 000004837) observed rabbits after application of a 13% EC product to the skin. The dermal exposure resulted in mild to severe erythema with no edema. The existing data are adequate to assign the 13% EC product tested to Toxicity Category II for primary dermal irritation. Currently registered products between 12% and 28% a.i. should also be assigned to Category II for primary dermal irritation. No data are available for assessing the primary dermal irritation of any EC product between 65% and 68% a.i., or any EC product which contains Aspon® plus other active ingredients.

BIBLIOGRAPHY


| MRID | CITATION |
|---|---|
| 000004835 | Bullock, C.H.; Narcisse, J.K. 1974. The eye irritation potential of Ortho Chinch Bug Spray (CC 5109): S-668: SOCAL 588/XX:24. (Unpublished study received Aug. 5, 1974 under 239-765; submitted by Chevron Cehmical Co., Richmond, Calif.; CDL:022718-A). |
| 000004833 | Gregory, L.K.; Narcisse, J.K. 1974. The eye irrtiation potential of CC-5495: S-745: SOCAL 674/XX:117. (Unpublished study received June 25, 1975 under 239-765; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:220001-C). |
| 000004836 | Narcisse, J.K. 1972. Eye irritation potential of Ortho Bug Spray: S-362: SOCAL 283/VI:114. (Unpublished study received Nov. 14, 1974 under 239-765; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:051023-A). |
| 000004837 | Narcisse, J.K. 1972. Skin irritation potential of Ortho Chinch Bug Spray: S-363: SOCAL 284B/VI:114. (Unpublished study received Nov. 14, 1974 under 239-765; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:051023-B). |
| 000004838 | Rittenhouse, J.R.; Narcisse, J.K. 1972. The acute dermal toxicity of Ortho Chinch Bug Spray: S-363: SOCAL 284A/VI:117. (Unpublished study received Nov. 14, 1974 under 239-765; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:051023-C). |

## VI. Ecological Effects

DISCIPLINARY REVIEW

Ecological Effects Profile
Required Labeling

### Ecological Effects Profile

The available data show that a 13% EC is highly toxic to fish and freshwater aquatic invertebrates, the invertebrates being more sensitive than fish.

Tests on a 13% EC indicate that there is no phytotoxicity to turf grass if used at recommended rates (3.7 pounds a.i. per acre), and that it is only slightly phytotoxic to certain varieties of turf at 2 to 4 times recommended rates.

### Required Labeling

Based on data discussed in the Manufacturing-Use section of this document, all EC products must bear the label warning: "This pesticide is toxic to fish. Do not contaminate water by cleaning of equipment or disposal of wastes."

TOPICAL DISCUSSIONS

Applicants for registration of end-use EC products are not required to submit information on ecological effects. The following discussions present supplemental information available to the Agency on EC formulations.

### Terrestrial Plants

Tests on a 13% EC (Chevron, 1971, MRID 000004849) indicate that there is no phytotoxic response by turfgrasses

## VI. Ecological Effects

DISCIPLINARY REVIEW

Ecological Effects Profile
Required Labeling

### Ecological Effects Profile

The available data show that a 13% EC is highly toxic to fish and freshwater aquatic invertebrates, the invertebrates being more sensitive than fish.

Tests on a 13% EC indicate that there is no phytotoxicity to turf grass if used at recommended rates (3.7 pounds a.i. per acre), and that it is only slightly phytotoxic to certain varieties of turf at 2 to 4 times recommended rates.

### Required Labeling

Based on data discussed in the Manufacturing-Use section of this document, all EC products must bear the label warning: "This pesticide is toxic to fish. Do not contaminate water by cleaning of equipment or disposal of wastes."

TOPICAL DISCUSSIONS

Applicants for registration of end-use EC products are not required to submit information on ecological effects. The following discussions present supplemental information available to the Agency on EC formulations.

### Terrestrial Plants

Tests on a 13% EC (Chevron, 1971, MRID 000004849) indicate that there is no phytotoxic response by turfgrasses

when used at the recommended rate of 3.7 pounds a.i. per acre. The response to the EC varies from no reaction to moderate phytotoxic symptoms when used at 2 to 4 times the recommended rate, depending on the variety of turfgrass tested (Lindemann 1974). This type of data is not, at present, required for registration.

Aquatic Invertebrates

A 48-hour toxicity test (EPA, 1975, MRID GS0019-011) using a 13% EC formulation was performed on the water flea, Daphnia magna. The 48-hour LC-50 = 0.625 ppm (0.5 to 0.77 ppm, 95% c.i.). These data are sufficient to characterize a 13% EC formulation as highly toxic to aquatic invertebrates.

Freshwater Fish

Data discussed in the section on Manufacturing-use products indicate that Aspon® can be considered very highly toxic to coldwater and warmwater fish species.

Addtional data, which are summarized in Table 7, are also available on the 96-hour LC-50 of a 13% EC formulation. These data indicate that the 13% EC formulation tested is highly toxic to rainbow trout.

Table 7. Acute Toxicity of Formulated Aspon® Products to Freshwater Fish

| Species | Formulation | LC-50 (ppm) | Reference |
|---|---|---|---|
| Rainbow Trout | 13% EC | 1.0 | EPA, 1975, MRID GS0019-011 |

BIBLIOGRAPHY


| MRID | CITATION |
|---|---|
| 00000 4849 | Chevron Chemical Co. 1971. Summary: Ortho Sod Webworm Control. (Unpublished study including OR 513 report nos. 387-1, 387-41, 621-37, 621-36, 623-07, 623-06, 504-23, received Dec. 20, 1971 under 239-2389; CDL:001557-A). |
| GS0019-011 | EPA. 1975. Report on the toxicity of Ortho Sod Webworm (13% active ingredient) to Daphnia magna. (U.S. EPA, Chemical and Biological Investigations Branch, Beltsville, Maryland, Static jar test No. 865, 8/21/75, unpublished.) |
| GS0019-012 | EPA. 1975. Report on the toxicity of Ortho Sod-Webworm 13% active ingredient to rainbow trout. (U.S. EPA, Chemical and Biological Investigations Branch, Beltsville, Maryland, Static jar test No. 848, 7/8/75, unpublished report.) |
| 00000 5003 | Lindemann, R.H.; Massey, V.C.; Coltharp, J.L.; Bryant, W.F. 1974. Product performance report: OR report no. 657-10. (Unpublsihed study including OR-513 report nos. 705-41, 748-21, 748-22, 705-25, 705-23 and 705-42, received June 25, 1975 under 239-2389; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:133068-C). |

# GRANULAR ASPON®

## I. Regulatory Position

### A. Regulatory Decision

The Agency has reviewed all data available to it. Although incomplete, these data indicate that granular Aspon® is suitable for registration because it does not meet or exceed the risk criteria leading to a Rebuttable Presumption Against Registration [Chapter 40, Section 162.11(a) of the Code of Federal Regulations]. Data gaps have been identified; when these data are supplied, the Agency will again review the registration status of this compound.

The Agency has determined that granular Aspon® does not appear to cause an unreasonable adverse effect with proper label directions and precautions. Those granular products currently registered may be reregistered subject to the conditions imposed for data requirements, and new products may also be registered under the terms of this Standard.

### B. Criteria for Registration Under the Standard

To be registered under this Standard, granular Aspon® products must meet the following conditions:

1. The granular product contains Aspon® as an active ingredient [if an unregistered source of Aspon® is used in formulating, then the data outlined under Section 162.18-2(c)(d)(1)(iii) will be required];



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2. The granular Aspon® product is within the acute toxicity limits for restricted or general use and bears the required labeling;

3. The granular Aspon® product is within acceptable ranges for use patterns and application methods; and

4. The applicant for registration of granular products complies with all other terms and conditions specified in this Standard and hereby offers to pay compensation to other persons, with regard to approval of this application, to the extent required by 3(c)(1)(d) and 3(c)(2)(d) of the Federal Insecticide, Fungicide, and Rodenticide Act [FIFRA], as amended, 7 U.S.C. 136(c)(1)(d) and 136(c)(2)(D).

C. Acceptable Ranges and Limits

1. Product Composition Standards

To be covered under this Standard, all granular products must contain Aspon® [O,O,O,O-Tetrapropyl dithiopyrophosphate] as an active ingredient. The Agency will consider for registration granular products which contain any percentage of active ingredient. In addition, currently registered and proposed granular products must agree to submit or cite the information on product composition identified as data gaps in Section I.D of this document

Standards have not yet been set for contaminants and inerts in granular Aspon® products. When standards are set for any contaminants or inerts in granular Aspon® products, granular end-use products must comply with those standards.

2. Acute Toxicity Limits

a. Restricted Use

The Agency will grant registration to granular Aspon® products as restricted pesticides (i.e., for retail sale to and application only by Certified Applicators or persons under their direct supervision) for non-food, outdoor use which have a Toxicity Category I rating for any of the following acute effects:

1) Acute Oral Toxicity;

2) Acute Dermal Toxicity;

3) Acute Inhalation Toxicity;

4) Primary Eye Irritation; or

5) Primary Dermal Irritation.

b. Non-Domestic Use

The Agency will grant registration to granular Aspon® products intended for non-domestic, non-food, outdoor use which have a Toxicity Category II rating for any of the following acute effects:

1) Acute Oral Toxicity;

2) Acute Dermal Toxicity; or

3) Acute Inhalation Toxicity;

The Agency will grant registration to granular Aspon® products intended for non-domestic, non-food, outdoor use which have a Toxicity Category I or II rating for either of the following acute effects:

1) Primary Eye Irritation; and

2) Primary Dermal Irritation.

c. Domestic Use

The Agency will grant registration to granular Aspon® products intended for domestic, non-food, outdoor use which have a Toxicity Category III or IV rating for any of the following acute effects:

1) Acute Oral Toxicity;

2) Acute Dermal Toxicity; or

3) Acute Inhalation Toxicity;

The Agency will grant registration to granular Aspon® products intended for domestic, non-food, outdoor use which have a Toxicity Category I through IV rating for either of the following acute effects:

1) Primary Eye Irritation; and

2) Primary Dermal Irritation.

3. Use Patterns and Application Methods

To be covered under this Standard, granular products may be used only as an insecticide on home lawns or ornamental turf. Application may not be made aerially. Currently registered granular products must retain present recommendations for dosage rates on the labels. Applicants who wish to increase the dosage recommendations on currently registered products, or who wish to register new products with higher dosage recommendations than those currently registered may be required to submit additional supporting data.

D. Data Gaps

To be covered under this Standard, applicants for registration or reregistration of granular Aspon® products

must agree to submit or cite the following information on the physical/chemical composition and toxicity of each proposed product. After each data gap is listed the section in the Proposed Guidelines which describes that type of data and when it is required [43 FR, No. 132, 29696 of July 10, 1978; and 43 FR, No. 163, 37336 of August 22, 1978].

| | Guidelines Section |
|---|---|
| Product Chemistry | |
| 1) Product Identity | 163.61-3(a) |
| 2) Disclosure of Ingredients | 163.61-3(c) |
| 3) Description of Manufacturing Process | 163.61-4 |
| 4) Formation of Unintentional Ingredients | 163.61-5 |
| 5) Declaration of Limits | 163.61-6(a) |
| 6) Certification of Limits | 163.61-6(b) |
| 7) Analytical Methods | 163.61-7(a) |
| 8) Analytical Results | 163.61(b)(1) |
| 9) Color | 163.61-8(c)(1) |
| 10) Odor | 163.61-8(c)(2) |
| 11) Density or Specific Gravity | 163.61-8(c)(8) |
| 12) Storage Stability | 163.61-8(c)(12) |
| 13) Oxidizing or Reducing Action | 163.61-8(c)(14) |
| 14) Explosiveness | 163.61-8(c)(15) |
| 15) Corrosion Characteristics | 163.61-8(c)(18) |
| *Toxicology | |
| Granulars Between 1% and 6% | |
| 1) Acute Inhalation (rat)** | 163.81-3 |

* A demonstration that a granular Aspon® product has a composition substantially similar to a granular product for which the Agency already has acceptable acute toxicity data will satisfy acute toxicity data requirements for the former product. Both active and inert ingredients will be considered in making determinations of similarity.

** An acute inhalation toxicity study is required for granular products if "20 percent or more of the aerodynamic equivalent of the formulated product (as registered or under conditions of use) is composed of particulates not larger than 10 microns in diameter" [Guidelines Section 163.81-3(a)(2)(ii)]. An acute inhalation test on any currently registered granular product between 1% and 6% a.i. may be submitted or cited in support of the registrations of all currently registered granular products. A request for a waiver of this requirement based on percent of particulates not larger than 10 microns must be made individually for each product.

E. Required Labeling

1. Product Chemistry

The ingredient statement will list the active ingredient as: O,O,O,O-Tetrapropyl dithiopyrophosphate. In all cases, the percentages by weight of active ingredient and inerts must equal 100%.

| | |
|---|---|
| Active Ingredient: | |
| O,O,O,O-Tetrapropyl dithiopyrophosphate..... | % |
| Inert Ingredients..... | % |
| Total..... | 100% |

2. Human Hazard - Precautionary Labeling

The hazard warnings and first aid statements on all granular product labels must correspond to the Toxicity Category assigned to that product for each acute effect (see Appendix A). Specifically, all currently registered granulars between 1% and 6% a.i. must carry on the label the acute toxicity hazard warnings and first aid statements required for the following Toxicity Categories:

Granulars Without Fertilizer
1) Acute Oral Toxicity - III
2) Acute Dermal Toxicity - III
3) Primary Eye Irritation - III
4) Primary Dermal Irritation - III

Granulars With Fertilizer
1) Acute Oral Toxicity - III
2) Acute Dermal Toxicity - III
3) Primary Eye Irritation - II
4) Primary Dermal Irritation - III

3. Environmental Fate

Because the use pattern clearly indicates the possibility of post-application exposure to children and pets, the

following warning must appear on all granular labels: "Keep children and pets off treated areas for 48 hours after application and until the grass has completely dried." Other environmental precautions not in conflict with specific parts of this Standard should be retained.

4. Environmental Hazards

All granular products must bear the label warning: "This pesticide is toxic to fish. Do not contaminate water by cleaning of equipment or disposal of wastes."

II. Regulatory Rationale

A. Regulatory Decision

The Agency has determined that granular Aspon® products described in this Standard can be registered for sale, distribution, and use in the United States. There are no data currently available to the Agency which suggest that Aspon® meets any of the risk criteria for unreasonable adverse effects as listed in 40 CFR 162.11(a). In addition, to be registered under this Standard, applicants must agree to submit or cite the data listed in Section I.D of this document, and must also upon meet the standards for use as listed in Section I.C.2 of this document.

B. Acceptable Ranges and Limits

1. Product Composition Standards

The Agency will consider for registration granular products which contain any percentage of Aspon® as an active ingredient as long as the products meet the acute toxicity standards listed in Section I.C.2 for domestic, non-domestic, or restricted use. The Agency considers that the use restrictions and required protective clothing for the several acute toxicity levels will adequately protect humans and the environment from unreasonable adverse effects.

2. Acute Toxicity Limits

a. Restricted Use

The Agency will register granular Aspon® products for restricted, non-food, outdoor use which have a Toxicity



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Category I rating because certified applicators can legitimately be expected to provide the specialized protective clothing (for themselves or those under their supervision) which are required for products with Toxicity Category I rating.

b. Non-Domestic Use

The Agency will register granular Aspon® products for non-domestic, non-food, outdoor use which have a Toxicity Category II rating for acute oral, dermal, or inhalation toxicity, or which have a Toxicity Category I or II rating for primary eye or dermal irritation, because non-domestic users can legitimately be expected to provide the specialized protective clothing (for themselves or their employees) which are required for products with these Toxicity Category ratings. The Agency considers that these restrictions, together with use of the required protective clothing, will adequately protect humans from unreasonable adverse effects.

c. Domestic Use

The Agency will register granular Aspon® products for domestic, non-food, outdoor use which have a Toxicity Category III or IV rating for acute oral, dermal, or inhalation toxicity, or which have a Toxicity Category I through IV rating for primary eye or dermal irritation. Granular products intended for domestic use with Toxicity Category I or II ratings for primary eye or dermal irritation must meet the criteria for child-resistant packaging [see FR 44(48):

13019-13024, March 9, 1979]. The Agency considers that the economic and aesthetic benefits from Aspon® use outweigh the risks from products with acute Toxicity Category ratings of III or IV, and that the use of child-resistant packaging for products with Toxicity I or II ratings for primary eye or dermal irritation will adequately protect humans from unreasonable adverse effects.

3. Use Patterns and Application Methods

Granular Aspon® products may be registered for use as an insecticide only on lawns and ornamental turf. Granular products may not be used on food crops because the hazard of such uses and of residue ingestion has not been evaluated nor has such an evaluation been requested. Application may not be made aerially because this method can reasonably be expected to result in high exposures to applicators, other persons, or wildlife close to the application site. Currently registered granular products must retain the dosage recommendations on the labels, in the absence of data to support higher rates.

C. Data Gaps

The data on the physical/chemical composition and acute toxicity which applicants are required to submit or cite for granular Aspon® products are listed in Section I.D of this document. These data are required in order to obtain registration for any proposed end-use product.

D. Required Labeling

Acute toxicity hazard warnings must accurately reflect the product's level of toxicity (products may not be labeled to show either greater or lesser hazard from the product than in fact exists). Because the use pattern indicates the possibility of exposure to children and pets, all granular Aspon® products must carry the following warning: "Keep children and pets off treated areas for 48 hours and until grass has completely dried."

III. Product Chemistry

DISCIPLINARY REVIEW

Chemistry Profile
Data Gaps
Required Labeling

Chemistry Profile

"Aspon®" is a trade name for O,O,O,O-tetrapropyl dithiopyrophosphate. No data are available on the physical/-chemical characteristics of any granular formulation.

Data Gaps

Listed below are the Product Chemistry data which must be submitted or cited to obtain registration or re-registration for granular Aspon® products. After each data gap is listed the section in the Proposed Guidelines (July 10, 1978, 43 FR, No. 132, 29696) which describes that type of data and when it is required.

| | Guidelines Section |
|---|---|
| 1) Product Identity | 163.61-3(a) |
| 2) Disclosure of Ingredients | 163.61-3(c) |
| 3) Description of Manufacturing Process | 163.61-4 |
| 4) Formation of Unintentional Ingredients | 163.61-5 |
| 5) Declaration of Limits | 163.61-6(a) |
| 6) Certification of Limits | 163.61-6(b) |
| 7) Analytical Methods | 163.61-7(a) |
| 8) Analytical Results | 163.61(b)(1) |
| 9) Color | 163.61-8(c)(1) |
| 10) Odor | 163.61-8(c)(2) |
| 11) Density or Specific Gravity | 163.61-8(c)(8) |
| 12) Storage Stability | 163.61-8(c)(12) |
| 13) Oxidizing or Reducing Action | 163.61-8(c)(14) |
| 14) Explosiveness | 163.61-8(c)(15) |
| 15) Corrosion Characteristics | 163.61-8(c)(18) |

Required Labeling

Ingredient Statement: The ingredient statement will list the active ingredient as O,O,O,O-Tetrapropyl dithiopyrophosphate.

TOPICAL DISCUSSIONS

Corresponding to each of the Topical Discussions listed below is the number of the section in the 'Proposed Guidelines for Registering Pesticides' of July 10, 1978 (43 FR, No. 132, 29696), which explains the minimum Product Chemistry data needed in order to obtain registration or reregistration for granular Aspon® products.

| | Guidelines Section |
|---|---|
| Chemical Identity | 163.61-3 |
| Manufacturing Processes | 163.61-4 |
| Formation of Unintentional Ingredients | 163.61-5 |
| Ingredients in Pesticide Products | 163.61-6 |
| Product Analytical Methods and Data | 163.61-7 |
| Physical/Chemical Properties | 163.61-8 |

Chemical Identity

At present, there is no acceptable common name for the insecticide, O,O,O,O-Tetrapropyl dithiopyrophosphate. For a discussion of other identifiers of this active ingredient, see the Product Chemistry chapter in the section of this document on manufacturing-use products.

Manufacturing Process

The Agency has no information on present-day manufacturing processes for any granular product.

Formation of Unintentional Ingredients

The Agency has no information on the possible formation of unintentional ingredients in any granular product.

Ingredients in Pesticide Products

For all pesticide products, the Agency requires a listing of the upper and lower limits established (by the

producer or formulator) for each active ingredient, and the upper limit for each impurity, reaction product, and degradation product which is known to be present or which might reasonably be identified. Currently registered granular products range from 1.32% to 5% a.i.

Product Analytical Methods and Data

No methods for analysis of granular products have been submitted or reported.

Physical/Chemical Properties

Color: There are no data available on any granular formulation.

Odor: There are no data available on any granular formulation.

Physical State: Granular products are in solid form.

Density or Specific Gravity: There are no data available on any granular formulation.

Storage Stability: There are no data available on any granular formulation.

Oxidizing or Reducing Action: No data are available on any granular formulation.

Explosiveness: No data are available on any granular formulation.

Corrosion Characteristics: No data are available on any granular formulation.

## IV. Environmental Fate

DISCIPLINARY REVIEW

Environmental Fate Profile
Exposure Profile
Required Labeling

### Environmental Fate Profile

There are no data currently available on the environmental fate of Aspon®.

### Exposure Profile

Because of the lack of environmental fate data for Aspon®, the Agency can make only brief generalizations about the possibility and extent of exposure.

For persons involved in the application of granular products, there is little chance of oral exposure except through accidental ingestion. Aspon® is not registered for use on food or feed crops, so there is very little possibility of dietary exposure to the general public. (Depending on the leaching and mobility characteristics of the granular products, home use may result in contamination of home garden vegetables.) Dermal and eye exposure to granular formulations (and to dust particles of the formulations) can occur. Inhalation exposure to granular formulations can also occur through inhalation of dust-sized particles by applicators and homeowners.

### Required Labeling

Although there are no data available on the environmental fate of Aspon® from which to determine label precautions,



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the use pattern (on home lawns) clearly indicates the possibility of post-application exposure to children and pets. The following warning must therefore appear on all granular labels:

> "Keep children and pets off treated areas for 48 hours after application and until the grass has completely dried."

V. Toxicology

DISCIPLINARY REVIEW

Toxicology Profile
Toxicology Hazard Assessment
Data Gaps
Required Labeling

Toxicology Profile

The acute oral toxicity in rats (males, >6.0 g/kg; females = 3.4 g/kg) indicates a potentially low acute oral toxicity in humans for the 3.2-3.9% granular product tested. The acute dermal toxicity in rabbits (4.65 g/kg) indicates a potentially low acute dermal toxicity in humans for the 5% granular tested. No data were available to assess the acute inhalation toxicity of any granular product. Data are insufficient to assess the full range of acute toxicity of all granular formulations.

An eye irritation study conducted on rabbits indicates a mild, transitory eye irritation potential for humans from the 3.2% granular (without fertilizer) tested. A study conducted on rabbits to assess primary dermal irritation indicates a slight, transitory dermal irritation potential for humans from the 3.2% granular tested. Data on other active ingredient products which contain fertilizer indicate a possible increase in the primary eye irritation potential of such products from the fertilizer component.

Toxicology Hazard Assessment

The 'Exposure Profile' which appears in the Environmental Fate chapter lists the chance of exposure to granular

products as small with some (unknown) possibility of dietary exposure from residues on home garden crops. The acute oral toxicity of a 3.9% granular product is low. Whether possible oral exposure to granular products would occur at levels high enough to be of concern cannot be determined, because of the lack of data.

Similarly, although some chance of inhalation exposure to granular products exists, dependant on the size of the dust particles of the formulations, no inhalation toxicology hazard assessment can be made for any granular product because of the lack of data.

Application of granular products can result in dermal exposure to applicators and homeowners, including ocular exposure from dust particles of the product. In addition, for home uses, children and pets may be exposed to treated lawns. The amount of exposure cannot be determined because of data gaps on the environmental fate of Aspon®. Data indicate that a 3.2% a.i. granular product has low acute dermal toxicity and low primary dermal irriation. The primary eye irriation potential of a 5% a.i. granular product is also low. Whether possible dermal and eye exposure to granular products would occur at levels high enough to be of concern cannot be determined because of the lack of data.

Data Gaps

Listed below are the Toxicology data which must be submitted or cited to obtain registration or re-registration

for granular Aspon® products.* After each data gap is listed the Section in the Proposed Guidelines of August 22, 1978 (43 FR, No. 163, 37336) which describes that type of data and when it is required. The Agency has determined that currently registered granular products between 1% and 6% a.i. are substantially similar in composition, except that currently registered granular Aspon® products between 1% and 6% a.i. which contain fertilizer will be considered substantially similar in composition for determining primary eye irritation. Acute toxicity data available on any one product in either group may be cited in support of the registration of any other product in that group, provided compensation has been offered for use of these data.

| | Guidelines Section |
|---|---|
| Granulars Between 1% and 6% | |
| 1) Acute inhalation (rat)**..... | 163.81-3 |

* A demonstration that a granular Aspon® product has a composition substantially similar to a granular product for which the Agency already has acceptable acute toxicity data will satsify acute toxicity data requirements for the former product. Both active and inert ingredients will be considered in making determinations of similarity.

** An acute inhalation toxicity study is required for granular products if "20 percent or more of the aerodynamic equivalent of the formulated product (as registered or under conditions of use) is composed of particulates not larger than 10 microns in diameter" [Guidelines Section 163.81-3(a)(2)(ii)]. An acute inhalation test on any currently registered granular product between 1% and 6% a.i. may be submitted or cited in support of the registrations of all currently registered granular products. A request for a waiver of this requirement based on percent of particulates not larger than 10 microns must be made individually for each product.

Required Labeling

Product-specific acute toxicity precautionary labeling is required. Acceptable categories of acute toxicity, and the corresponding required precautionary statements, appear in Appendix A to this document.

TOPICAL DISCUSSIONS

Corresponding to each of the Topical Discussions listed below is the number of the section in the 'Proposed Guidelines' of August 22, 1978 (43 FR, No. 163, 37336) which explains the minimum Toxicology data needed in order to obtain registration or reregistration for granular Aspon® products.

| | Guidelines Sections |
|---|---|
| Acute Effects | 163.81-1, -2, and -3 |
| Local Irritation | 163.81-4 and -5 |

Acute Effects

Acute Oral Toxicity

The minimum data requirement for testing acute oral toxicity (LD-50) is one test on any registered product between 1% and 6% a.i., preferably using the laboratory rat. The acute oral LD-50 for a 3.2-3.9% a.i. granular is 6.0 g/kg for male rats and 3.4 g/kg for female rats (Eisenlord, 1978, MRID 000004857). The data indicate that the 3.2-3.9% granular tested should be assigned Toxicity Category III for acute oral toxicity. Currently registered products between 1% and 6% a.i. should also be assigned to Category III for acute oral toxicity.

Acute Dermal Toxicity

The minimum data requirement for testing acute dermal toxicity (LD-50) is one test, preferably using the albino rabbit, for any registered product between 1% and 6% a.i. The acute dermal LD-50 for a 5% granular in rabbits is 4.65 g/kg (Bullock, 1970, MRID 000004858). No skin irritation or signs of toxicity were noted at this dose level. The data indicate that the 5% granular tested should be assigned Toxicity Category III for acute dermal toxicity. Currently registered products between 1% and 6% a.i. should also be assigned to Category III for acute dermal toxicity.

Acute Inhalation Toxicity

The minimum data requirement for testing acute inhalation toxicity (LC-50) is one test for any registered product between 1% and 6% a.i., preferably using the laboratory rat. An acute inhalation toxicity study is required for granular products if "20 percent or more of the aerodynamic equivalent of the formulated product (as registered or under conditions of use) is composed of particulates not larger than 10 microns in diameter" [Guidelines Section 163.81-3(a)(2)(ii)]. An acute inhalation test on any currently registered granular product between 1% and 6% a.i. may be submitted or cited in support of the registrations of all currently registered granular products. A request for a waiver of this

requirement based on percent of particulates not larger than 10 microns must be made individually for each product. No data are available for assessing the acute inhalation LC-50 of any granular product.

Local Irritation

Primary Eye Irritation

The minimum data requirement for testing primary eye irritation is one test for a registered product from each group of substantially similar products, conducted on a mammal, preferably the albino rabbit (unless the pesticide product has a pH of 1-3 or 12-14 or demonstrates severe skin corrosivity). Data which demonstrate that the test substance has a pH of 1-3 or 12-14 will be submitted instead of data from a primary eye irritation test. For all regulatory purposes, the Agency will assume that substances with the above pH values or which cause Category I skin effects are corrosive (i.e., have a Toxicity Category I rating). [For purposes of determining primary eye irritation potential, the Agency has determined that there are two groups of substantially similar granular Aspon® products: 1) those between 1% and 6% a.i. which do not contain fertilizer, and 2) those between 1% and 6% a.i. which do contain fertilizer.]

A primary eye irritation study was conducted on rabbits using a 3.2% granular without fertilizer (Bullock,

1976, MRID 000004861). The application (0.1 ml) of the 3.2% granular in the eye resulted in moderate, transient conjunctival redness and a slight discharge of the conjunctivae at 1 hour; all eyes were normal at 24 hours. In addition, no corneal opacity was observed. The data are adequate to assign the 3.2% granular tested to Toxicity Category III for primary eye irritation. Currently registered products between 1% and 6% a.i. which do not contain fertilizer should also be assigned to Category III for primary eye irritation.

Data available on non-Aspon® products with fertilizer indicate that such products should be assigned to Toxicity Category II for primary eye irritation (The Andersons [sic], 1980, GS0019-019; Biesemeior, 1978, GS0019-020; O.M. Scott & Sons, Co., 1979, GS0019-021; O.M. Scott & Sons, Co., 1979, GS0019-022; Raltech Scientific Services, Inc., 1980, GS0019-023; Thompson, 1980, GS0019-024; Thompson, 1979, GS0019-025; Thompson, 1980, GS0019-026). In the absence of specific data, the Agency assumes that Aspon® products with fertilizer should also be assigned to Toxicity Category II for primary eye irritation. When the data requested on product chemistry of granular products have been submitted, the Agency will review those data to determine substantial similarity of composition, in which case Category II will be assigned. If similarity cannot be established,

additional testing will be required of the applicant to establish an appropriate eye irritation toxicity category. Registrants also have the option of submitting data on the pH of their product (if appropriate) or submitting data from a primary eye irritation test on their specific product.

Primary Dermal Irritation

The minimum data requirement for testing primary dermal irritation is one test for any registered product between 1% and 6% a.i., conducted on a mammal, preferably the albino rabbit. Eisenlord (1978, MRID 000004859) observed rabbits after application of a 3.2% granular product to the skin. Transient, slight erythema with and without edema was observed at 24 and 48 hours; however all animals were normal at 72 hours. The data are adequate to assign the 3.2% granular tested to Toxicity Category III for primary dermal irritation. Currently registered products between 1% and 6% a.i. should also be assigned to Category III for primary dermal irritation.

BIBLIOGRAPHY


| MRID | CITATION |
|---|---|
| 00000 4858 | Bullock, C.H. 1970. Toxicology lab report--T 1520; T 1549. (Unpublished study received Apr. 18, 1978 under 239-2032; prepared by Stauffer Chemical Co., submitted by Chevron Chemical Co., Richmond, Calif.; CDL:234497-C). |
| 00000 4861 | Bullock, C.H. 1976. The eye irritation potential of CC 7187: S-972; SOCAL 937/27:76. (Unpublished study received Apr. 18, 1978 under 239-2032; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:234497-F). |
| 00000 4857 | Eisenlord, G.H. 1978. The acute oral toxicity of Ortho Chinch Bug and Sod Webworm Control: S-1178; SOCAL 1179/31: 116. (Unpublished study received Apr. 18, 1978 under 239-2032; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:234497-B). |
| 00000 4859 | Eisenlord, G.H. 1978. The skin irritation potential of Ortho Chinch Bug and Sod Webworm Control: S-1179; SOCAL 1180/30:132. (Unpublished study received Apr. 18, 1978 under 239-2032; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:234497-D). |

Addenda

| MRID | CITATION |
|---|---|
| GS0019-019 | The Andersons [sic]. 1979. Primary eye irritation study in the albino rabbit, primary skin irritation study in the albino rabbit, acute dermal toxicity study in the albino rabbit, acute oral toxicity study in rats - Turf Care 20-4-10 with Benefin and chlorpyrifos. (Unpublished studies, received May 30, 1979, under 9198-37). |
| GS0019-020 | Biesemeior, J. 1978. Toxicology lab report [acute oral LD-50, acute dermal LD-50, skin irritation, eye irritation] reference no. F-8649. (Unpublished study received Apr. 24, 1979, under 538-156; prepared by Raltech Scientific Services, Inc. [Warf Institute, Madison, Wis.]; submitted by O.M. Scott & Sons, Marysville, Ohio). |
| GS0019-021 | O.M. Scott & Sons, Co. 1979. Acute oral toxicity, acute dermal toxicity, primary eye irritation, primary dermal irritation - Kwit and Western Lawn Insect Control. (Unpublished studies received May 5, 1980, under 538-69.) |
| GS0019-022 | O.M. Scott & Sons, Co. 1979. Acute oral toxicity, acute dermal toxicity, primary eye irritation, primary dermal irritation - Western Lawn Insect Control Plus Fertilizer. (Unpublished study received May 5, 1980, under 538-94.) |
| GS0019-023 | Raltech Scientific Services, Inc. 1980. Eye irritation, Lab report 760871. (Unpublshed study received May 1, 1980 under 538-137; submitted by O.M. Scott & Sons Co., Marysville, Ohio.) |
| GS0019-024 | Thompson, G.W. 1980. The primary eye irritation study of F6713. (Unpublished study received June 12, 1980, under 538-72; prepared by Raltech Scientific Services, Inc.; submitted by O.M. Scott & Sons, Marysville, Ohio. Accession # 243155.) |
| GS0019-025 | Thompson, G.W. 1979. Toxicology lab report - F9348. (Unpublished study received Nov. 6, 1979, under 538-160; prepared by Raltech Scientific Services, Inc.; submitted by O.M. Scott & Sons, Marysville, Ohio. Accession # 241350.) |
| GS0019-026 | Thompson, G.W. 1980. Toxicology lab report (acute oral LD-50, acute dermal LD-50, skin irritation and eye irritation), lab report 765242. (Unpublished study received March 24, 1980, under 538-163; prepared by Raltech Scientific Services, Inc.; submitted by O.M. Scott & Sons, Marysville, Ohio.) |

## VI. Ecological Effects

DISCIPLINARY REVIEW

Ecological Effects Profile
Required Labeling

### Ecological Effects Profile

Information on the acute toxicity of a granular form to laboratory mammals is supplied in the Toxicology chapter. The toxicity of a 3.2% formulation ranges from "slightly" to "practically non-toxic" to rats. A 3.2% granular is moderately toxic to warmwater fish. Tests on a 3.2% granular formulation indicate no phytotoxic response by turf when the product is applied at 14.6 pounds a.i. per acre, which is 4 times the recommended rate.

### Required Labeling

Based on data discussed in the Manufacturing-Use section of this document, all granular products must bear the label warning: "This pesticide is toxic to fish. Do not contaminate water by cleaning of equipment or disposal of wastes."

TOPICAL DISCUSSIONS

Applicants for registration of end-use granular products are not required to submit information on ecological effects. The following discussions present supplemental information available to the Agency on granular formulations.

### Terrestrial Plants

Tests on a 3.2% granular product (Chevron, 1974, MRID 000004854) indicate no phytotoxic response by turf when

exposed to 14.6 pounds a.i. per acre, which is 4 times the recommended rate. This type of data is not, at present, required for registration.

Freshwater Fish

Data discussed in the section on Manufacturing-use products indicate that Aspon® can be considered very highly toxic to coldwater and warmwater fish species.

Additional data, which are summarized in Table 3, are also available on the 96-hour LC-50 of a 3.2% granular formulation. The data indicate that the 3.2% granular is moderately toxic to bluegills.

Table 3. Acute Toxicity of Formulated Aspon® Products to Freshwater Fish

| Species | Formulation | LC-50 (ppm) | Reference |
|---|---|---|---|
| Bluegill | 3.2% Gran. | 5.6 | EPA, 1975, MRID GS0019-013 |
| Bluegill | 3.2% Gran. | 3.8 | EPA, 1975, MRID GS0019-014 |

BIBLIOGRAPHY


| MRID | CITATION |
|---|---|
| 00000 4854 | Chevron Chemical Co. 1974. Aspon, Dursban (Unpublished study including report nos. 627.02, 627.27, 623.09-623.12, 504.23, 504.26, 366.10, 658.29, 657.35, 519.23, 748.20, 727.23, 519.30, 727.24, 727.30, 627.23, 627.24, received May 6, 1975 under 239-2032; CDL:222347-C). |
| GS0019-013 | EPA. 1975. Report on the toxicity of Ortho Chinch Bug Control, 3.2% a.i., to bluegills. (U.S. EPA, Beltsville, Maryland, Static jar test No. 876, 9/22/75, unpublished report.) |
| GS0019-014 | EPA. 1975. Report on the toxicity of Ortho Chinch Bug Control on bluegills. (U.S. EPA, Chemical and Biological Investigations Branch, Beltsville, Maryland, Static jar test No. 866, 8/21/75, unpublished.) |

Guide to Use of This Bibliography

1. Content of Bibliography. This bibliography contains citations of all the studies reviewed by EPA in arriving at the positions and conclusions stated elsewhere in this Standard. The bibliography is divided into 3 sections: (1) citations that contributed information useful to the review of the chemical and considered to be part of the data base supporting registrations under the Standard, (2) citations examined and judged to be inappropriate for use in developing the Standard, and (3) standard reference material. Primary sources for studies in this bibliography been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions, and the published technical literature.

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OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base
Supporting Registrations Under the Standard

Product Chemistry

| MRID | CITATION |
|---|---|
| 000004843 | Chevron Chemical Company. 1975. Product research and services: shelf-life test - Ortho Chinch Bug Lawn Spray. (Unpublished study received Dec. 3, 1975 under 239-2445; CDL:228761-A) |
| GS0019-001 | Ja, W., W.J. Smith, and J.F. Below. 1966. The analysis of technical Aspon, Richmond report no. RR-66-35. Stauffer Chemical Co., New York, N.Y. |
| 005004395 | Keith, L.H.; Garrison, A.W.; Alford, A.L. 1968. The high resolution NMR spectra of pesticides. I. organophosphorus pesticides. J. Assoc. Off. Anal. Chem. 51(5):1063-1094. |
| 005001354 | McMahon, B.; Bourke, J.A. 1978. Analytical behavior data for chemicals determined using AOAC multi-residue methodology for pesticide residues in foods. J. Assoc. Off. Anal. Chem. 61:640-652. |
| 005002074 | Ruzicka, J.H.; Thomson, J.; Wheals, B.B.; Woods, N.F. 1968. The application of gel chromatography to the separation of pesticides. Part I. organophosphorus pesticides. J. Chromatog. 34(1):14-20. |
| GS0019-002 | Sittig, M. 1971. Agricultural chemicals manufacture. Noyes Data Corp., Park Ridge, N.J. |
| GS0019-003 | Sittig, M. 1977. Pesticides process encyclopedia. Noyes Data Corp., Park Ridge, N.J. |
| GS0019-004 | Stauffer Chemical Company. 1968. Aspon insecticide, technical information bulletin. New York, N.Y. |
| GS0019-005 | Stauffer Chemical Company. 1970. Infrared procedure to determine the assay of Aspon, method no. MPO 25-3. New York, N.Y. (Unpublished). |

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base
Supporting Registrations Under the Standard

Product Chemistry

| MRID | CITATION |
|---|---|
| 005004479 | Toy, A.D.F. 1951. Tetraethyl dithionopyrophosphate and related tetraaalkyl dithionopyrophosphates. J. Amer. Che. Soc. 73:4670-4674. |
| GS0019-006 | U.S. Patent No. 2,663,722. 1953. Method of preparing tetraalkyl dithionopyrophosphate. |

Toxicology

| | |
|---|---|
| 000004858 | Bullock, C.H. 1970. Toxicology lab report—T 1520; T 1549. (Unpublished study received Apr. 18, 1978 under 239-2032; prepared by Stauffer Chemical Co., submitted by Chevron Chemical Co., Richmond, Calif.; CDL:234497-C). |
| 000004861 | Bullock, C.H. 1976. The eye irritation potential of CC 7187: S-972; SOCAL 937/27:76. (Unpublished study received Apr. 18, 1978 under 239-2032; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:234497-F). |
| 000004835 | Bullock, C.H.; Narcisse, J.K. 1974. The eye irritation potential of Ortho Chinch Bug Spray (CC 5109): S-668: SOCAL 588/XX:24. (Unpublished study received Aug. 5, 1974 under 239-765; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:022718-A). |
| 000004857 | Eisenlord, G.H. 1978. The acute oral toxicity of Ortho Chinch Bug and Sod Webworm Control: S-1178; SOCAL 1179/31:116. (Unpublished study received Apr. 18, 1978 under 239-2032; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:234497-B). |
| 000004859 | Eisenlord, G.H. 1978. The skin irritation potential of Ortho Chinch Bug and Sod Webworm Control: S-1179; SOCAL 1180/30:132. (Unpublished study received Apr. 18, 1978 under 239-2032; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:234497-D). |

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base
Supporting Registrations Under the Standard

Toxicology

| MRID | CITATION |
|---|---|
| 000004833 | Gregory, L.K.; Narcisse, J.K. 1974. The eye irritation potential of CC-5495: S-745; SOCAL 674/XX:117. (Unpublished study received June 25, 1975 under 239-765; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:220001-C). |
| 000004836 | Narcisse, J.K. 1972. Eye irritation potential of Ortho Bug Spray: S-362; SOCAL 283/VI:114. (Unpublished study received Nov. 14, 1974 under 239-765; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:051023-A). |
| 000004837 | Narcisse, J.K. 1972. Skin irritation potential of Ortho Chinch Bug Spray: S-363; SOCAL 284B/VI:114. (Unpublished study received Nov. 14, 1974 under 239-765; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:051023-B). |
| 000004838 | Rittenhouse, J.R.; Narcisse, J.K. 1972. The acute dermal toxicity of Ortho Chinch Bug Spray: S-363; SOCAL 284A/VI:117. (Unpublished study received Nov. 14, 1974 under 239-765; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:051023-C). |

Ecological Effects

| | |
|---|---|
| GS0019-007 | EPA. 1975. Report on the toxicity of technical Aspon to rainbow trout. (U.S. EPA, Chemical and Biological Investigations Branch, Beltsville, Maryland, Static jar test No. 913, unpublished report.) |
| GS0019-008 | EPA. 1976. Report on the toxicity of Aspon technical to rainbow trout. (U.S. EPA, Chemical and Biological Investigations Branch, Beltsville, Maryland, Static jar test No. 932, unpublished.) |

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base
Supporting Registrations Under the Standard

Ecological Effects

| MRID | CITATION |
|---|---|
| GS0019-009 | EPA. 1976. Report on the toxicity of Aspon technical to bluegill sunfish. (U.S. EPA, Chemical and Biological Investigations Branch, Beltsville, Maryland, Static jar test No. 998, 7/14/76, unpublished report.) |
| 000004831 | Fink, R.; Reno, F.E. 1976. Final report: eight-day dietary LC-50--bobwhite quail: project no. 132-129. (Unpublished study received March 8, 1976 under 476-2163; prepared by Hazleton Laboratories America, Inc. in cooperation with Maryland Dept. of Agriculture, Div. of Inspection and Regulation, submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:225231-A). |
| GS0019-010 | Hill, E.F.; Heath, R.G.; Spann, J.W.; Williams, J.D. 1975. Lethal dietary toxicities of environmental pollutants to birds. Special Scientific Report--Wildlife No. 191. U.S. Fish and Wildlife Service, Washington, D.C. |
| 000004830 | Joiner, R.L. 1975. Safety evaluation of Aspon technical by a five-day feeding test in mallard ducks: T-5397. (Unpublished study received June 26, 1975 under 476-2163; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:223289-A). |

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base
Supporting Registrations Under the Standard

Toxicology - Addenda

| MRID | CITATION |
|---|---|
| GS0019-019 | The Andersons [sic]. 1979. Primary eye irritation study in the albino rabbit, primary skin irritation study in the albino rabbit, acute dermal toxicity study in the albino rabbit, acute oral toxicity study in rats - Turf Care 20-4-10 with Benefin and chlorpyrifos. (Unpublished studies, received May 30, 1979, under 9198-37). |
| GS0019-020 | Biesemeior, J. 1978. Toxicology lab report [acute oral LD-50, acute dermal LD-50, skin irritation, eye irritation] reference no. F-8649. (Unpublished study received Apr. 24, 1979, under 538-156; prepared by Raltech Scientific Services, Inc. [Warf Institute, Madison, Wis.]; submitted by O.M. Scott & Sons, Marysville, Ohio). |
| GS0019-021 | O.M. Scott & Sons, Co. 1979. Acute oral toxicity, acute dermal toxicity, primary eye irritation, primary dermal irritation - Kwit and Western Lawn Insect Control. (Unpublished studies received May 5, 1980, under 538-69.) |
| GS0019-022 | O.M. Scott & Sons, Co. 1979. Acute oral toxicity, acute dermal toxicity, primary eye irritation, primary dermal irritation - Western Lawn Insect Control Plus Fertilizer. (Unpublished study received May 5, 1980, under 538-94.) |
| GS0019-023 | Raltech Scientific Services, Inc. 1980. Eye irritation, Lab report 760871. (Unpublshed study received May 1, 1980 under 538-137; submitted by O.M. Scott & Sons Co., Marysville, Ohio.) |
| GS0019-024 | Thompson, G.W. 1980. The primary eye irritation study of F6713. (Unpublished study received June 12, 1980, under 538-72; prepared by Raltech Scientific Services, Inc.; submitted by O.M. Scott & Sons, Marysville, Ohio. Accession # 243155.) |

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base
Supporting Registrations Under the Standard

Toxicology - Addenda

| MRID | CITATION |
|---|---|
| GS0019-025 | Thompson, G.W. 1979. Toxicology lab report - F9348. (Unpublished study received Nov. 6, 1979, under 538-160; prepared by Raltech Scientific Services, Inc.; submitted by O.M. Scott & Sons, Marysville, Ohio. Accession # 241350.) |
| GS0019-026 | Thompson, G.W. 1980. Toxicology lab report (acute oral LD-50, acute dermal LD-50, skin irritation and eye irritation), lab report 765242. (Unpublished study received March 24, 1980, under 538-163; prepared by Raltech Scientific Services, Inc.; submitted by O.M. Scott & Sons, Marysville, Ohio.) |

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Examined and Judged Inappropriate For
Use in Developing the Standard

| MRID | CITATION |
|---|---|
| 00500409Ø | Bagdon, R.E.; DuBois, K.P. 1955. Pharmacologic effects of chlorthion, malathion and tetrapropyl dithionopyrophosphate in mammals. Arch. Inter. Pharmacod. Therap. CIII(2/3):192-199. |
| 000004829 | Bresolin, P.M. 1975. Toxicology laboratory report T-5284: Aspon technical. (Unpublished study received Dec. 5, 1975 under 476-2163; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:223288-A). |
| 000004853 | Chevron Chemical Company. 19??. Summary statement: Ortho Chinch Bug and Sod Webworm Control. Summary of studies 222347-B through 222347-C. (Unpublished study received May 6, 1975 under 239-2032; CDL:222347-A). |
| 000004855 | Chevron Chemical Company. 19??. Summary statement: Ortho Sod Webworm Control. Summary of studies 222348-B through 222348-C. (Unpublished study received Apr. 18, 1975 under 239-2389; CDL:222348-A). |
| 000004841 | Chevron Chemical Company. 19??. Summary table: efficacy data at 3.7 lb Ai/A (Aspon). (Unpublished study received March 31, 1960 under 239-765; CDL:222167-B). |
| 000004849 | Chevron Chemical Company. 1971. Summary: Ortho Sod Webworm Control. (Unpublished study including OR 513 report nos. 378-1, 387-41, 621-37, 621-36, 623-07, 623-06, 504-23, received Dec. 20, 1971 under 239-2389; CDL:001557-A). |
| 000004842 | Chevron Chemical Company. 1974[?]. Summary statement: Ortho Chinch Bug Spray. Summary of studies 2222170-B through 222170-C. (Unpublished study received Apr. 24, 1975 under 239-765; CDL:222170-A). |
| 000004854 | Chevron Chemical Company. 1974. Aspon, Dursban. (Unpublished study including report nos. 627.02, 627.27, 623.09-623.12, 504.23, 504.26, 366.10, 658.29, 657.35, 519.23, 748.20, 727-23, 519.30, 727.24, 727.30, 627.23, 627.24, received May 6, 1975 under 239-2032; CDL:222347-C). |

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Examined and Judged Inappropriate For
Use in Developing the Standard

| MRID | CITATION |
|---|---|
| 00000 4832 | Chevron Chemical Company. 1975. Summary statement. Summary of study 220001-D. (Unpublished study received June 25, 1975 under 239-765; CDL:220001-A). |
| 000004847 | Chevron Chemical Company. 1975. Summary statement-- phytotoxicity: Ortho Chinch Bug Lawn Spray. Summary of study 2288758-B. (Unpublished study received Dec. 3, 1975 under 239-2445; CDL:228758-A). |
| 000004845 | Chevron Chemical Company. 1975. Summary statement - phytotoxicity: Ortho Sod Webworm Lawn Spray. Summary of study 228762-B. (Unpublished study received Dec. 16, 1975 under 239-2446; CDL:228762-A). |
| 000004850 | Chevron Chemical Company. 1975. Summary statement: Aspon. Summary of study 133068-C. (Unpublished study received June 25, 1975 under 239-2389; CDL:133068-A). |
| GS0019-011 | EPA. 1975. Report on the toxicity of Ortho Sod Webworm (13% active ingredient) to Daphnia magna. (U.S. EPA, Chemical and Biological Investigations Branch, Beltsville, Maryland, Static jar test No. 865, 8/21/75, unpublished.) |
| GS0019-012 | EPA. 1975. Report on the toxicity of Ortho Sod-Webworm 13% active ingredient to rainbow trout. (U.S. EPA, Chemical and Biological Investigations Branch, Beltsville, Maryland, Static jar test No. 848, 7/8/75, unpublished report.) |
| GS0019-013 | EPA. 1975. Report on the toxicity of Ortho Chinch Bug Control, 3.2% a.i., to bluegills. (U.S. EPA, Beltsville, Maryland, Static jar test No. 876, 9/22/75, unpublished report.) |
| GS0019-014 | EPA. 1975. Report on the toxicity of Ortho Chinch Bug Control on bluegills. (U.S. EPA, Chemical and Biological Investigations Branch, Beltsville, Maryland, Static jar test No. 866, 8/21/75, unpublished.) |

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Examined and Judged Inappropriate For
Use in Developing the Standard

| MRID | CITATION |
|---|---|
| 000005003 | Lindemann, R.H.; Massey, V.C.; Coltharp, J.L.; Bryant, W.F. 1974. Product performance report: OR-513 report no. 657-10. (Unpublished study including OR report nos. 705-41, 748-21, 748-22, 705-25, 705-23 and 705-42, received June 25, 1975 under 239-2389; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:133068-C). |
| 000004848 | Pate, D.A. 1967. Ortho Chinch Bug Control with fertilizer. (Unpublished study including OR-513 report nos. 238-40, 238-41, 237-20, 230-47, 234-5, 234-2, 230-26, 230-49, received May 6, 1968 under 239-2265; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:001512-A). |
| 000005377 | Radeleff, R.D.; Woodard, G.T. 1957. The toxicity of organic phosphorus insecticides to livestock. J. Amer. Vet. Med. Assoc. 130(5):215-216. |
| 000004860 | Rittenhouse, J.R. 1978. The acute inhalation toxicity of Ortho Chinch Bug and Sod Webworm Control: S-1180; SCCAL 1181/28:142. (Unpublished study received Apr. 18, 1978 under 239-2032; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:234497-E). |
| 000004834 | Sherman, M.; Chang, M.T.Y.; Herrick, R.B. 1969. Fly control, chronic toxicity, and residues from feeding propyl thiopyrophosphate to laying hens. J. Econ. Entomol. 62(6):1494-1499. |
| 005004694 | Sherman, M; Ross, E.; Chang, M.T.Y. 1964. Acute and subacute toxicity of several organophosphorus insecticides to chicks. Toxicol. Appl. Pharmacol. 6(2):147-153. |

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Standard Reference Material


| MRID | CITATION |
|---|---|
| | Chemline, Chemical Information on Line [Data base]. Bethesda, Md: National Library of Medicine. March 1980. |
| GS0019-015 | EPA. 1976. EPA manual of chemical methods for pesticides and devices. AOAC, Arlington, Virginia. |
| GS0019-016 | EPA. 1979. Pesticide chemical use pattern profile for Aspon. Washington, D.C. (Unpublished). |
| GS0019-017 | Martin, H.; Worthing, C.R., eds. 1977. Pesticide index: basic information on the chemicals used as active components of pesticides. 5th ed. British Crop Protection Council, Worcestershire, England. |
| GS0019-018 | Spencer, E.Y. 1973. Guide to the chemicals used in crop protection. 6th ed. Canada Dept. of Agriculture, Ontario, Canada. |

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Appendix A

Table 1. Required Toxicity Category Warning Statements for Aspon® Products

| Exposure Route | Toxicity Category I | Toxicity Category II | Toxicity Category III | Toxicity Category IV |
|---|---|---|---|---|
| Oral* | Fatal if swallowed. Wash throroughly with soap and water after handling and before eating or smoking. | May be fatal if swallowed. Wash thoroughly with soap and water after handling and before eating or smoking. | Harmful if swallowed. Wash thoroughly after handling. | No precautionary statement required. |
| Dermal* | Fatal if absorbed through skin. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Wash thoroughly after handling and before eating or smoking. Remove contaminated clothing and wash before reuse. | May be fatal if absorbed through skin. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Wash thoroughly with soap and water after handling and before eating or smoking. Remove contaminated clothing and wash before reuse. | Harmful if abosrbed through skin. Avoid contact with skin, eyes, or clothing. Wash thoroughly after handling. | No precaautionary statement required. |
| Inhalation* | Fatal If Inhaled. Do not breathe dust (vapor or spray mist). Wear a mask or pesticide respirator jointly approved by the Mining Enforcement and Safety Administration (formerly the U.S. Bureau of Mines) and the National Institute for Occupational Safety and Health. Remove contaminated clothing and wash before reuse. | May be fatal If Inhaled. Do not breathe dust (vapor or spray mist). Wear a mask or pesticide respirator jointly approved by the Mining Enforcement and Safety Administration (formerly the U.S. Bureau of Mines) and the National Institute for Occupational Safety and Health. Remove contaminated clothing and wash before reuse. | Harmful If Inhaled. Avoid breathing dust (vapor or spray mist). Remove contaminated clothing and wash before reuse. Keep container closed when not in use. Use only with adequate ventilation. | No precautionary statement required. |

Appendix A

Table 1. Required Toxicity Category Warning Statements for Aspon® Products

| Exposure Route | Toxicity Category I | Toxicity Category II | Toxicity Category III | Toxicity Category IV |
|---|---|---|---|---|
| Eye effects | Corrosive. Causes eye damage. Harmful or fatal if swallowed. Do not get in eyes, or on clothing. Wear goggles, or face shield. Wash thoroughly after handling. Remove contaminated clothing and wash before reuse. | Causes eye irritation. Harmful if swallowed. Do not get in eyes or on clothing. Wash thoroughly after handling. Remove contaminated clothing and wash before reuse. | Avoid contact with eyes or clothing. Wash thoroughly after handling. | No precautionary statement required. |
| Skin effects | Corrosive. Causes burns. Do not get on skin or on clothing. Wear protective clothing and rubber gloves.# Wash thoroughly after handling. Remove contaminated clothing and wash before reuse. | Causes skin irritation. Do not get on skin or on clothing. Wash thoroughly after handling. Remove contamined clothing and wash before reuse. | Avoid contact with skin or clothing. Wash thoroughly after handling. | No precautionary statement required. |
| Signal Word | DANGER | WARNING | CAUTION | CAUTION |

* Any product which falls into Toxicity Category I for the oral, dermal, or inhalation acute toxicity categories will be required to carry the word "Poison" on the label with a skull and crossbones.

# The need for gloves must be determined on an individual basis. Some products cause blistering if confined under clothing.

Appendix A

Table 2. Required First Aid Statements

| Exposure Route | Toxicity Category I | Toxicity Category II | Toxicity Category III | Toxicity Category IV |
|---|---|---|---|---|
| Oral | If swallowed: Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. Do not give anything by mouth to an unconscious person. Get medical attention. For ECs with >10% petroleum distillates: If the patient is unconscious, maintain breathing and heart beat (CPR:cardiopulmonary resuscitation). Contact your local Poison Control Center, hospital, or physician immediately. If the patient is conscious, induce vomiting (syrup of ipecac; if not available, stimulate the back of throat with finger). Never give anything by mouth to an unconscious person! | Same as for Toxicity Category I. For ECs with >10% petroleum distillates: If the patient is unconscious, maintain breathing and heart beat (CPR:cardiopulmonary resuscitation). Contact your local Poison Control Center, hospital, or physician immediately. [The question whether to induce vomiting will be determined on a case-by case basis.] | Same as for Toxicity Category I. For ECs with >10% petroleum distillates: If the patient is unconscious, maintain breathing and heart beat (CPR:cardiopulmonary resuscitation). Contact your local Poison Control Center, hospital, or physician immediately. [The question whether to induce vomiting will be determined on a case-by case basis.] | No first aid statement required. For ECs with >10% petroleum distillates: If the patient is unconscious, maintain breathing and heart beat (CPR:cardiopulmonary resuscitation). Contact your local Poison Control Center, hospital, or physician immediately. Do not induce vomiting! |
| Dermal | If on skin: Wash with plenty of soap and water. | Same as for Toxicity Category I. | Same as for Toxicity Category I. | No first aid statement required. |
| Inhalation | If inhaled: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention. | Same as for Toxicity Category I. | Same as for Toxicity Category I. | No first aid statement required. |

Table 2. Required First Aid Statements CONTINUED

| Exposure Route | Toxicity Category I | Toxicity Category II | Toxicity Category III | Toxicity Category IV |
|---|---|---|---|---|
| Eye effects | If in eyes: Flush with water for 15 minutes. Get medical attention. If swallowed: Drink promptly a large quantity of milk, egg whites, gelatin solution, or, if these are not available, drink large quantities of water. Avoid alcohol. NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. | Same as for Category I, except omit Note to Physician. | If on skin: Wash with plenty of soap and water. Get medical attention if irritation persists. | No first aid statement required. |
| Skin effects | If on skin: Wash with water. Get medical attention. If swallowed: Drink promptly a large quantity of milk, egg whites, gelatin solution, or, if these are not available, drink large quantities of water. Avoid alcohol. NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. | Same as for Category I, except omit Note to Physician. | If on skin: Wash with plenty of soap and water. Get medical attention if irritation persists. | No first aid statement required. |

*U.S. GOVERNMENT PRINTING OFFICE: 1980 341-085/3945